08-08-06

AF

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of:

Anthonius J. Swaak

Serial No.: 08/817,704

Filed: August 25, 1997

For: USE OF ERYTHROPOIETIN IN THE TREATMENT OF RHEUMATOID ARTHRITIS

Examiner: G. Ewoldt, Ph.D.

Group Art Unit: 1644

Attorney Docket No.: 2183-7195US

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BRIEF ON APPEAL

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This brief is submitted as a single copy pursuant to 37 C.F.R. § 41.37 and in the format required by 37 C.F.R. § 41.37(c) (1):

08/09/2006 TBESHAH1 00000023 08817704
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1) REAL PARTY IN INTEREST

The real party in interest is Roche Diagnostics Corporation, 9115 Hague Road, Indianapolis, IN 46250, Reel/Frame 009971/0915 and Reel/Frame 008739/0058.

2) REALTED APPEALS AND INTERFERENCES

Neither the Appellant, the Appellant's representative, nor the Assignee is aware of any pending appeal or interference which would directly affect, be directly affected by, or have any bearing on the Board's decision in the present pending appeal.

3) STATUS OF THE CLAIMS

Claims 1 through 17, 19, 21, 22, 27 through 30, 32 and 33 were cancelled without prejudice or disclaimer.

Claims 18, 20, 23-26, 31, and 34-36 stand rejected.

No claims are allowed

The rejection of claims 18, 20, 23-26, 31, and 34-36 is being appealed.

4) STATUS OF AMENDMENTS

On June 7, 2006, Appellant filed an Amendment requesting an amendment to claims 18 and 20 to correct typographical errors. The proposed amendments were entered on July 7, 2006.

5) SUMMARY OF THE CLAIMED SUBJECT MATTER

The invention includes a method of treating morning stiffness, loss of grip strength, painful joints, or swollen joints in a rheumatoid arthritis patient suffering from morning stiffness, loss of grip strength, painful joints, or swollen joints. (*See*, Specification, WO 96/14081, Page 3, lines 3-17, page 17, lines 14-16, and throughout the examples). The method of the claimed invention includes identifying a patient that suffers from morning stiffness, loss of grip strength, painful joints and swollen joints. (*See*, Specification, WO 96/14081, Page 6, lines 3-11, page 17, lines 14-16). An effective amount of erythropoietin is administered to the patient over a treatment period. (*See*, Specification, WO 96/14081, Abstract and Page 2, lines 6-11 and lines 31-32, page 17, lines 1-25). The method further includes identifying that the patient has, after the treatment period in comparison to before the treatment period, a lower level of morning stiffness, loss of grip strength, painful joints, or swollen joints. (*See*, Specification, WO 96/14081, Page 4, line 25 to Page 5, line 12; Page 7, line 34 to Page 8, line 19, page 12, lines 1-11, page 13, lines 1-12).

The invention also includes a method of ameliorating an erythrocyte sedimentation rate or C-reactive protein level in a rheumatoid arthritis patient in need of such amelioration. (*See*, Specification, WO 96/14081, Page 3, lines 3-17, page 7, lines 19-31, page 11, lines 1-12, and throughout the examples). The method includes identifying a patient that is in need of amerlioration (*See*, Specification, WO 96/14081, Page 6, lines 3-11) and administering to the patient an erythrocyte sedimentation rate or C-reactive protein level activity ameliorating effective amount of erythropoietin over a period of time. (*See*, Specification, WO 96/14081, Abstract and Page 2, lines 6-11 and lines 31-32). The method further includes identifying that the erythrocyte sedimentation rate or C-reactive protein level in the patient has been ameliorated. (*See*, Specification, WO 96/14081, Page 4, line 25 to Page 5, line 12; Page 7, line 34 to Page 8, line 19).

6) GROUNDS OF REJECTION TO BE REVIEWED

A. Whether claims 18, 20, 23-26, 31, and 34-36 are unpatentable under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.

7) ARGUMENT

(i) 35 U.S.C. § 112, first paragraph, written description, new matter

Claims 18, 20, 23 through 26, and 31 through 36 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. It was thought that the claims include new matter. The two independent claims, claims 18 and 20, are argued on this appeal. The dependent claims will not be argued separately and are considered to be allowable upon allowance of the respective independent claim.

To comply with the written description require of 35 U.S.C. § 112, first paragraph, each claim limitation must be expressly, implicitly, or inherently support in the originally filed disclosures. MPEP § 2163(II)(A)(3)(b). Further, the subject matter of the claim need not be described literally, *in haec verba*, in order for the disclosure to comply with the written description requirement. MPEP § 2163.02.

a. Claims 18, 23, 24, 34 and 36

The Examiner contends that the "specification and claims as originally filed do not provide support for the invention as now claimed, specifically:

> A) a method of treating consisting of identifying a patient (now an RA patient), administering EPO to said patient, and identifying that said patient that suffers from morning stiffness, loss of grip strength, painful joints, or swollen joints has a lower level of morning stiffness, loss of grip strength, painful joints, or swollen joints after treatment."

(Office Action, mailed December 16, 2005, page 2).

The basis for this statement is that the specification allegedly lacks *in haec verba* support for claim 18. Specifically, it was thought that the specification only discloses that the elements of claim 18 in the examples in the context of treating chronic anemia associated with rheumatoid arthritis ("ACD") patients, with a specific dosage of erythropoietin ("EPO"), for a specific timeframe. (*Id.*) While, it was thought that ACD rheumatoid arthritis patients are a distinct from rheumatoid arthritis ("RA") patients as a whole, no support has been cited for this contention. (*Id.*) Moreover, the Examiner admits that one of ordinary skill in the art would recognize an

ACD patient to be a specific subset of RA patients. (*Id.*). These statements are inconsistent and cannot sustain the present rejection.

Furthermore, the Examiner's asserted basis for the rejection (that the specification does state claim 18 verbatim) has been repeatedly rejected by the Court of Appeals for the Federal Circuit ("Federal Circuit"). The Federal Circuit has long cautioned that the written description requirement "is not subsumed by the 'possession' inquiry." *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 63 USPQ2d 1609, 1617 (Fed. Cir. 2002). Identity of description is not necessary. *See, e.g.*, *Crown Operations Int'l, Ltd. v. Solutia Inc.*, 62 USPQ2d 1917, 1922 (Fed. Cir. 2002) ("[T]he disclosure as originally filed does not have to provide *in haec verba* support for the claimed subject matter at issue."). Identity of that which is described, however, is necessary: "What is claimed by the patent application must be the same as what is disclosed in the specification ...." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 122 S. Ct. 1831, 1840, 62 USPQ2d 1705 (2002); *accord Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997). Here, the originally filed specification provides a written description of methods of treating all RA patients.

It was thought that because the examples included ten (10) ACD RA patients, Appellant's method should be limited to ACD RA patients. (Office Action, mailed December 16, 2005, page 2). The specification clearly discusses methods including a broader range of subjects. For example, the as-filed claims are not restricted to ACD RA patients. Specifically, originally filed claim 5 recites "[u]se of erythropoietin or a substance having erythropoietin-like activity in the preparation of a pharmaceutical for the treatment of symptoms associated with rheumatoid arthritis." (WO 96/14801, page 17).

Indeed, insufficient evidence has been presented by the Examiner that one skilled in the art would read the as-filed specification as being limited to ACD RA patients. The examiner has the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims. *In re Wertheim*, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976). This burden has not been satisfied. One of ordinary skill in the art would recognize that the method of claim 18 has general applicability to RA patients. In fact, the Abstract clearly states "A particular benefit is seen in patients suffering from rheumatoid arthritis" and beginning on page 5, line 32 of

WO96/14081, that the methods of the present invention are "focused on the effects of r-hu-EPO on RA disease activity parameters."

Additionally, the as-filed specification recites:

> The invention thus provides the use of erythropoietin or a substance having erythropoietin-like activity in the preparation of a pharmaceutical for the treatment of chronic inflammations, especially those related to (auto-)immune diseases, ***in particular RA. In RA we found an overall improvement in the clinical parameters for scoring disease activity.*** Most impressive are the results on clinical variables such as painscore and morning stiffness as disclosed below. A significant decrease in the number of tender joints was already observed after two weeks of treatment. The changes in other clinical parameters did not reach statistical significance due to the wide range of values and the small number of patients in the study. However, when the parameters were expressed as a percentage of their baseline value, significant improvements were observed.

(WO 96/14801, page 3, lines 3-17)(emphasis added). The specification does not limit the scope of the invention to ACD RA patients.

It was further thought that the claims should be restricted to human recombinant EPO. (Office Action, mailed December 16, 2005, page 3). Again, the specification is not so limited. Originally submitted dependent claim 8 recites "Use according to anyone of the aforegoing claim[s] wherein the erythropoietin is human erythropoietin," while originally submitted claim 9 recites "Use according to anyone of the aforegoing claim[s] wherein the erythropoietin or substance having such activity is one of recombinant origin." (WO 96/14801, page 17, lines 21-25). Under the doctrine of claim differentiation, the as-filed specification clearly disclosed EPO other than human recombinant EPO. Further, the specification states:

> According to the invention any erythropoietin which has the ameliorating effect on chronic inflammations can be used. Preferably this erythropoietin is not immunogenic so that is can be administered repeatedly. This will usually lead to the use of human erythropoietin of any origin, although recombinant erythropoietin seems the product of choice because of its purity and constant quality. **On the other hand it may very well be possible to use non-human truncated forms of mammalian erythropoietin** as long as they have the activity and are not immunogenic upon normal administration to patients.

(*Id.*, page 3, lines 21-30, *see also,* Abstract)(emphasis added). In other words, the Specification also does not restrict the type of EPO used.

It was thought that the Specification lacked disclosure of "A method of treating morning stiffness, loss of grip strength, painful joints or swollen joints." (Office Action, mailed March 17, 2005, page 3). It was further thought that because the examples did not select patients "suffering from morning stiffness, loss of grip strength, painful joints, or swollen joints," that Appellant was precluded from claiming this element. (Office Action, mailed December 16, 2005, page 3). Such is not the case.

The originally-submitted claims included "use" claims. Appellant submitted the Declaration of Alan J. Howarth during prosecution as support that the "use" or "Swiss-type" claims, as originally filed, provide written support for a method of treating morning stiffness, loss of grip strength, painful joints, or swollen joints in a patient suffering from morning stiffness, loss of grip strength, painful joints, or swollen joints. Declaration of Alan J. Howarth, filed September 7, 2005. ("Howarth Declaration").

Methods of treatment are not literally patentable subject matter in Europe because of the European Patent Convention (EPC). Article 52 of the EPC defines patentable inventions as those that are susceptible of industrial application, which are new and which involve an inventive step. (*Id.*, at ¶10). A claim type that has developed to provide protection for methods of treatment without being *in haec verba* a method of treatment is the "Swiss-type" or "use" type claim language. Use claims developed because Article 52(4) EPC does not apply to products for use in any prohibited treatment methods. The claims have developed as a use of a substance or composition for the manufacture of a medicament for a specified new and inventive therapeutic application, or, as a claim to a known compound in an appropriate composition suitable for administration to a patient. Further, Articles 52(4) and 54 of the EPC specifically allow for the protection of product use with ultimate therapeutic methods of treatment, while at the same time adhering to the purpose of Article 52(4) EPC (*i.e.*, protecting physicians from the burdens of patent infringement in non-commercial and non-industrial activities). (*Id.*, ¶ 13).

In order to conform to proper U.S. practice, 'use' type claims or Swiss-type claims are amended because, strictly, 'use' claims may not be patentable in the US. However, converting the 'use' type claims into methods of treatment is what one of ordinary skill in the art would understand from the written description of the '704 application. (*Id.*, ¶15). Thus, originally filed claims 5 and 6 which recite, in part, "Use of erythropoietin or a substance having erythropoietin-

like activity" and "wherein the symptoms treated comprise at least one of the group of morning stiffness, painful and swollen joints, loss of grip strength and pain," provide support for "[a] method of treating morning stiffness, loss of grip strength, painful joints or swollen joints," provide support for a "method of treating morning stiffness, loss of grip strength, painful joints or swollen joints." (WO 96/14801, page 17).

Evidence and actual examples of methods of treatment are shown starting on page 6 of the as-filed specification. The various acts of the method claims are supported by this section. In addition to providing exemplary dosage and administration protocols, the specification notes that "clinical and laboratory evaluation was performed at entry and weekly by the same physician, till the end of the study, then at 9 and 12 weeks after onset of the study." (WO 96/14801, page 6, lines 20-36, page 7, line 32 – page 8, line 19). Thus, one of ordinary skill in the art would readily understand that measurements were taken to identify patients suffering from the various symptoms and that measurements were taken during and after the study to determine that the symptoms had been reduced by the treatment.

The as-filed specification also provides support for the claim element "identifying that a patient suffers from morning stiffness, loss of grip strength, painful joints, or swollen joints." There are numerous examples in the as-filed specification discussing measuring each of these elements in RA patients. For example, the specification states, "EPO is used . . . for the treatment of chronic inflammations" and "[a] particularly useful benefit is seen in patients suffering from rheumatoid arthritis (RA). Significant effects are seen in clinical variables such as **morning stiffness, swollen joints, and the like**" (WO 96/14801, abstract)(emphasis added).

The specification further provides:

> The invention thus provides the use of erythropoietin or a substance having erythropoietin-like activity in the preparation of a pharmaceutical for the treatment of chronic inflammations, especially those related to (auto-)immune diseases, in particular RA. In RA we found an overall improvement in the clinical parameters for scoring disease activity. Most impressive are the results on clinical variables such as **painscore and morning stiffness** as disclosed below. A significant decrease in the number of **tender joints** was already observed after two weeks of treatment. The changes in other clinical parameters did not reach statistical significance due to the wide range of values and the small number of patients in the study. However, when the parameters were expressed as a percentage of their baseline value, significant improvements were observed.

(WO 96/14801, page 3, lines 3-17)(emphasis added). Further, Table III on page 11, Table IV on page 12 and Table V on page 13 each demonstrate the effectiveness of such methods.

Originally submitted claim 6 recites "wherein the symptoms treated comprise at least one of the group of morning stiffness, painful and swollen joints, loss of grip strength and pain." (WO 96/14801, page 17). Painscore and morning stiffness measurements in RA patients are reflected in Table IV (WO 96/14801, page 12), while number of swollen joints and grip strength in RA patients are discussed on page 13 of the originally filed specification. It is stated that a "significant decrease in the number of tender joints was already observed after two weeks of treatment." (WO 96/14801, page 3, lines 11-12). Further, page 6, lines 16-19 of the specification even provides an exemplary treatment protocol. The as-filed specification clearly provides methods of treating patients with symptoms of at least one of the group of morning stiffness, painful and swollen joints, loss of grip strength and pain.

Additionally, the as-filed specification included claim 5 directed to use of erythropoietin to treat symptoms of "of at least one of the group of morning stiffness, painful and swollen joints, loss of grip strength and pain." Clearly, one skilled in the art would recognize that to treat symptoms of "at least one of the group of morning stiffness, painful and swollen joints, loss of grip strength and pain," patients having at least one of those conditions would first be identified. (*See also,* Howarth Declaration, ¶¶'s 16-18). The Examiner has failed to meet his initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in an applicant's disclosure a description of "identifying that a patient suffers from morning stiffness, loss of grip strength, painful joints, or swollen joints." *Wertheim*, 541 F.2d at 263, 191 USPQ at 97.

It was further thought that the specification lacked disclosure of "identifying or measuring painful joints." (Office Action, mailed December 16, 2005, at page 3). Appellant respectfully notes that originally filed claims are considered part of the specification. As stated, originally submitted claim 6 recites "wherein the symptoms treated comprise at least one of the group of morning stiffness, painful and swollen joints, loss of grip strength and pain." (WO 96/14801, page 17). Thus, a method where a pharmaceutical preparation is used for the treatment of the symptom of "painful joints" is clearly supported by the specification.

In view of the foregoing, Appellant respectfully submits that each and every element of claim 18 is supported in the specification and originally filed claims. Consequently, Appellant respectfully request that the rejection of claim 18 (and dependent claims 23, 24, 34 and 36 therefrom) under 35 U.S.C., first paragraph, as constituting new matter be withdrawn and the claims allowed.

b. Claims 20, 25, 26, 31 and 35

The Examiner contends that the "specification and claims as originally filed do not provide support for the invention as now claimed, specifically:

* * *

B) a method of ameliorating an erythrocyte sedimentation rate or C-reactive protein level consisting of identifying a patient (now an RA patient), administering Epo to said patient, and identifying that said patient has an ameliorated erythrocyte sedimentation rate or C-reactive protein level."

(Office Action, mailed December 16, 2005, page 2).

The basis for this statement is that the specification allegedly lacks *in haec verba* support for claim 20. Specifically, it was thought that the specification only discloses the elements of claim 20 in the context of treating a limited ACD subset of RA patients with recombinant human EPO. (*Id.*, page 3) While, it was thought that ACD rheumatoid arthritis patients are a distinct from rheumatoid arthritis ("RA") patients as a whole, no support has been cited for this contention. (*Id.*, page 2) Moreover, the Examiner admits that one of ordinary skill in the art would recognize an ACD patient to be a specific subset of RA patients. (*Id.*). These statements are inconsistent and cannot sustain the present rejection.

Furthermore, as stated herein, the Examiner's asserted basis for the rejection (that the specification does state claim 20 verbatim) has been repeatedly rejected by the Court of Appeals for the Federal Circuit ("Federal Circuit"). The Federal Circuit has long cautioned that the written description requirement "is not subsumed by the 'possession' inquiry." *Enzo Biochem,* 63 USPQ2d at 1617. Identity of description is not necessary. *See, e.g., Crown Operations Int'l,* 62 USPQ2d at 1922("[T]he disclosure as originally filed does not have to provide *in haec verba* support for the claimed subject matter at issue."). Identity of that which is described, however, is

necessary: "What is claimed by the patent application must be the same as what is disclosed in the specification ...." *Festo Corp.*, 535 U.S. at 736' *accord Lockwood*, 41 USPQ2d at1966 (Fed. Cir. 1997). Here, the originally filed specification provides a written description of methods of treating all RA patients.

It was thought that because Appellant's experiments were performed on ten (10) ACD RA patients, Appellant's method should be limited to ACD RA patients. (Office Action, mailed December 16, 2005, page 2). As stated herein, the specification clearly discusses methods including a broader range of subjects. For example, the as-filed claims are not restricted to ACD RA patients. Specifically, originally filed claim 5 recites "[u]se of erythropoietin or a substance having erythropoietin-like activity in the preparation of a pharmaceutical for the treatment of symptoms associated with rheumatoid arthritis." (WO 96/14801, page 17).

Indeed, insufficient evidence has been presented by the Examiner that one skilled in the art would read the as-filed specification as being limited to ACD RA patients. The examiner has the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims. *In re Wertheim*, 191 USPQ at 97. This burden has not been satisfied. One of ordinary skill in the art would recognize that the method of claim 18 has general applicability to RA patients. In fact, the Abstract clearly states "[a] particular benefit is seen in patients suffering from rheumatoid arthritis" and beginning on page 5, line 32 of WO96/14081, that the methods of the present invention are "focused on the effects of r-hu-EPO on RA disease activity parameters."

Additionally, the as-filed specification recites:

> The invention thus provides the use of erythropoietin or a substance having erythropoietin-like activity in the preparation of a pharmaceutical for the treatment of chronic inflammations, especially those related to (auto-)immune diseases, ***in particular RA. In RA we found an overall improvement in the clinical parameters for scoring disease activity.*** Most impressive are the results on clinical variables such as painscore and morning stiffness as disclosed below. A significant decrease in the number of tender joints was already observed after two weeks of treatment. The changes in other clinical parameters did not reach statistical significance due to the wide range of values and the small number of patients in the study. However, when the parameters were expressed as a percentage of their baseline value, significant improvements were observed.

(WO 96/14801, page 3, lines 3-17)(emphasis added). Appellant has not limited the scope of the invention to ACD RA patients.

It was further thought that the claims should be restricted to human recombinant EPO. (Office Action, mailed December 16, 2005, page 3). Again, the specification is not so limited. Originally submitted claim 8 recites "Use according to anyone of the aforegoing claim wherein the erythropoietin is human erythropoietin," while originally submitted claim 9 recites "Use according to anyone of the aforegoing claim wherein the erythropoietin or substance having such activity is one of recombinant origin." (WO 96/14801, page 17, lines 21-25). Under the doctrine of claim differentiation, the as-filed specification clearly disclosed EPO other than human recombinant EPO. Further, the specification states:

> According to the invention any erythropoietin which has the ameliorating effect on chronic inflammations can be used. Preferably this erythropoietin is not immunogenic so that is can be administered repeatedly. This will usually lead to the use of human erythropoietin of any origin, although recombinant erythropoietin seems the product of choice because of its purity and constant quality. **On the other hand it may very well be possible to use non-human truncated forms of mammalian erythropoietin** as long as they have the activity and are not immunogenic upon normal administration to patients.

(*Id.*, page 3, lines 21-30, *see also,* Abstract)(emphasis added). In other words, the specification also does not restrict the type of EPO used.

It was thought that the specification lacked disclosure of "[a] method of ameliorating an erythrocyte sedimentation rate or C-reactive protein level in a rheumatoid arthritis patient n need of such amelioration." (Office Action, mailed March 17, 2005, page 3). However, as stated, the originally-submitted claims included "use" claims. As supported by the Howarth Declaration and as described herein, the "use" or Swiss-type claims, as originally filed provide written support for a method of ameliorating an erythrocyte sedimentation rate or C-reactive protein level in a rheumatoid arthritis patient n need of such amelioration.

As previously stated, methods of treatment are not literally patentable subject matter in Europe because of the European Patent Convention (EPC). Article 52 of the EPC defines patentable inventions as those that are susceptible of industrial application, which are new and which involve an inventive step. (*Id.*, ¶ 10). A claim type that has developed to provide protection for methods of treatment without being *in haec verba* a method of treatment is the

Swiss-type or 'use' type claim language. Use claims developed because Article 52(4) EPC does not apply to products for use in any prohibited treatment methods. The claims have developed as a use of a substance or composition for the manufacture of a medicament for a specified new and inventive therapeutic application, or, as a claim to a known compound in an appropriate composition suitable for administration to a patient. Further, Articles 52(4) and 54 of the EPC specifically allow for the protection of product use with ultimate therapeutic methods of treatment, while at the same time adhering to the purpose of Article 52(4) EPC (i.e., protecting physicians from the burdens of patent infringement in non-commercial and non-industrial activities). (*Id.*, ¶ 13).

In order to conform to proper U.S. practice, 'use' type claims or Swiss-type claims are amended because, strictly, 'use' claims may not be patentable in the US. However, converting the 'use' type claims into methods of treatment is what one of ordinary skill in the art would understand from the written description of the '704 application. (*Id.*, ¶15). Thus, the originally filed claims in view of the disclosure in the specification of measuring the effect of EPO on erythrocyte sedimentation rate and C-reactive protein provide support for "[a] method of ameliorating an erythrocyte sedimentation rate or C-reactive protein level in a rheumatoid arthritis patient n need of such amelioration." (WO 96/14801, page 7, lines 19-31 and page 17).

Evidence and actual examples of methods of treatment are shown starting on page 6 of the as-filed specification. The various acts of the method claims are supported by this section. In addition to providing exemplary dosage and administration protocols, the specification notes that "clinical and laboratory evaluation was performed at entry and weekly by the same physician, till the end of the study, then at 9 and 12 weeks after onset of the study." Erythrocyte sedimentation rate (ESR) and C-reactive protein levels were measured. (*Id.*) Further, Table III on page 11, demonstrate the effectiveness of the various disclosed methods. Accordingly, the examples provide the written description support of a method of ameliorating an erythrocyte sedimentation rate or C-reactive protein level consisting of identifying a patient, administering Epo to the patient, and identifying that the patient has an ameliorated erythrocyte sedimentation rate or C-reactive protein level. Therefore, methods of treatment are literally supported by the specification and one of ordinary skill in the art would recognize that such methods are disclosed for the treatment of all patients with rheumatoid arthritis.

In view of the foregoing, Appellant respectfully submits that each and every element of claim 20 is supported in the specification and originally filed claims. Consequently, Appellant respectfully request that the rejection of claim 20 (and dependent claims 25, 26, 31 and 35 therefrom) under 35 U.S.C., first paragraph, as constituting new matter be withdrawn and the claims allowed.

8) CLAIMS APPENDIX

A copy of claims 18, 20, 23-26, 31, and 34-36 is appended hereto as Appendix B.

9) EVIDENCE APPENDIX

The Declaration of Alan J. Howarth, Ph.D., with attachments, as filed September 7, 2005, is appended hereto as Appendix A. The Examiner entered the Declaration on September 7, 2005 as acknowledged the Declaration in the Office Action mailed December 16, 2005 at page 2.

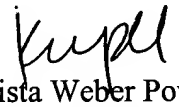
10) RELATED APPEALS APPENDIX

There is no related appeals appendix.

CONCLUSION

Appellant respectfully submits that claims 18, 20, 23-26, 31, and 34-36 are allowable. Appellant respectfully requests that the rejection of claims 18, 20, 23-26, 31, and 34-36 under 35 U.S.C. § 112, first paragraph, be reversed.

Respectfully submitted,



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Date: August 7, 2006

APPENDIX A

Evidence

PATENT

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In re Application of:

Anthonius J. Swaak

Serial No.: 08/817,704

Filed: August 25, 1997

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Examiner: G. Ewoldt, Ph.D.

Group Art Unit: 1644

Attorney Docket No.: 2183-7195US

NOTICE OF EXPRESS MAILING

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Person making Deposit: Steve Wong

Dear Sir:

Assistant Commissioner of Patents
Arlington, VA 22313

DECLARATION OF ALAN J. HOWARTH, Ph.D.

1. I hereby declare that all statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 17 U.S.C. §1001 and that such willful false statements may jeopardize the validity of the captioned application or any patent issued thereon.

2. My name is Alan J. Howarth. I am a named partner in the law firm of Clayton, Howarth & Cannon, P.C.. The firm is based in Cottonwood Heights, Utah, a suburb

of Salt Lake City. My practice mainly focuses on U.S. and foreign intellectual property and technology law, with emphasis on obtaining, enforcing, and defending patents, trademarks, copyrights, and trade secrets.

3. I hold a Bachelor of Science in Biological Sciences, a Master of Science in Plant Pathology, and Doctor of Philosophy in Plant Virology. My technical degrees are from the University of California-Davis. I later received a J.D. from Brigham Young University. I have 14 years of experience in biotechnology research and teaching, having held appointments at the University of California-Davis, the University of Illinois, and the University of Arizona. I have published scientific papers in the fields of virology, molecular genetics, enzymology, microbiology, and molecular evolution. Prior to co-founding my current firm, I was a patent attorney and partner in a Salt Lake area intellectual property firm. My practice focuses on U.S. and international patenting of inventions in the areas of biotechnology, pharmaceuticals, chemistry, and biomedical products.

4. I have practiced patent law for approximately twelve years, specifically including preparing and prosecuting patent applications in the pharmaceutical and biotechnology arts.

5. I am very familiar with the filing of applications from foreign jurisdictions that contain 'use' type claims, "Swiss-type" claims, and converting those claims to acceptable U.S. practice claims.

6. I was approached to provide an unbiased opinion as to whether USSN 08/817,704 (hereinafter referred to as the '704 application) provided written description

supporting the currently pending claims. In that regard, I have reviewed and am familiar with the contents of the '704 application, filed August 25, 1997 and titled Use of Erythropoietin in the Treatment of Rheumatoid Arthritis. Further, I have reviewed the originally filed Paris Cooperation Treaty application, PCT/NL95/00370 (hereinafter referred to as the '370 PCT application), and am familiar with its contents.

7. Further, I have reviewed and am familiar with the contents of Martin, Todd, PATENTABILITY OF METHODS OF MEDICAL TREATMENT: A COMPARATIVE STUDY, 82 J. Pat. & Trademark Off. Soc'y 381, 390 (June 2000)(*supra*)(hereinafter referred to as the Martin publication) and Petrova, Albena, From the Amazon to the Alps..., 15 Pace Int'l L. Rev 247, 250 (2003) citing Loi fédérale du 25 juin 1954 sur les brevets d'invention, Legge federale del 25 giugno 1954 sui brevetti d'invenzione, Bundesgesetz vom 25. Juni 1954 über die erfindungspatente [Switzerland Federal Law on Patents for Inventions], RO 1955 893, RU 1955 899, AS 1955 871, art. 7(c) (1954) (amended 1995)(*supra*) (hereinafter referred to as the Petrova publication).

8. In my opinion, the disclosure of the '704 application, including the 'use" or Swiss-type claims, as originally filed provides written support for a method of treating morning stiffness, loss of grip strength, painful joints, or swollen joints in a patient suffering from morning stiffness, loss of grip strength, painful joints, or swollen joints, and, a method of ameliorating an erythrocyte sedimentation rate or C-reactive protein level in a patient in need of such amelioration. In my opinion, the originally

submitted 'use' claims provide written description adequate to support these methods of treatment.

9. I base my opinion on my knowledge, experience, common practice in patent law, and on the two journal articles included with this Declaration.

10. I am aware that methods of treatment are not literally patentable subject matter in Europe because of the European Patent Convention (EPC). Article 52 of the EPC defines patentable inventions as those that are susceptible of industrial application, which are new and which involve an inventive step.

11. I am aware that the Examiner in the '704 application has rejected claims 18, 20, 23-26, and 31-36 under 35 USC §112, 1st ¶, as not having written support for methods of treatment. The Examiner basis his rejection on the argument that there is not *in haec verba* support for claim 18 and claim 20, the two independent claims, in the specification as originally filed.

12. The Martin publication teaches and discloses that the European Patent Convention (EPC) defines patentable inventions as those that are susceptible of industrial application, which are new and which involve an inventive step and that the 1973 Munich Convention specifically provided that the treatment of humans could represent independent inventions under Article 52. However, Article 52(4) EPC perpetuates a fiction that methods of medical treatment are incapable of industrial application and explicitly excludes such methods by creating the fiction that methods of treatment are not susceptible of industrial application.

13. A claim type that has developed to provide protection for methods of treatment without being *in haec verba* a method of treatment is the Swiss-type or 'use' type claim language. Use claims developed because Article 52(4) EPC does not apply to products for use in any prohibited treatment methods. The claims have developed as a use of a substance or composition for the manufacture of a medicament for a specified new and inventive therapeutic application, or, as a claim to a known compound in an appropriate composition suitable for administration to a patient. Further, Articles 52(4) and 54 of the EPC specifically allow for the protection of product use with ultimate therapeutic methods of treatment, while at the same time adhering to the purpose of Article 52(4) EPC (i.e., protecting physicians from the burdens of patent infringement in non-commercial and non-industrial activities).

14. My opinion is further supported by the Petrova article which provides that format particularly was established to claim methods of treatment. Reference to Swiss law defines Swiss-type claims as compounds subject of a prior right, which do not meet the prior art conditions with respect to their use for the implementation of a method of therapeutic treatment or diagnosis.

15. It is noted that in order to conform to proper U.S. practice, 'use' type claims or Swiss-type claims are amended because, strictly, 'use' claims may not be patentable in the US. However, converting the 'use' type claims into methods of treatment is what one of ordinary skill in the art would understand from the written description of the '704 application.

16. The underlying '370 PCT application specifically supports "treatment of chronic inflammations" as this phrase is found in the originally submitted claim 1. Further, originally submitted claim 6 of the '370 PCT application specifically supports "wherein the symptoms treated comprise at least one of the group of morning stiffness, painful and swollen joints, loss of grip strength and pain." Additionally, the originally filed specification clearly discloses that "EPO is used... for the treatment of chronic inflammations" and "[s]ignificant effects are seen in clinical variables such as morning stiffness, swollen joints, and the like" in the originally filed abstract of the '370 PCT application.

17. Page 3, lines 11-12, of the originally submitted specification specifically supports a "significant decrease in the number of tender joints was already observed after two weeks of treatment." The treatment protocol is specifically provided for on page 6, lines 16-19, of the originally submitted '370 PCT specification. Accordingly, in my opinion, the new matter rejections should be removed.

18. The examples of the '370 PCT application disclose various methods of treatment including identifying that a patient that suffers from morning stiffness, loss of grip strength, painful joints, or swollen joints has a lower level of morning stiffness, loss of grip strength, painful joints, or swollen joints after treatment. Specifically, the methods disclose page 6 of the as-filed specification, methods of "Treatment" are clearly described. The various acts of the method claims are supported by this section. In addition to providing exemplary dosage and administration protocols, the specification notes that "clinical and laboratory evaluation was performed at entry and

weekly by the same physician, till the end of the study, then at 9 and 12 weeks after onset of the study." Erythrocyte sedimentation rate (ESR) was measured by the Westergren method. Assessments of the Ritchie index, grip strength, number of swollen joints, morning stiffness and a subjective pain score (visual analogue scale 0-10 points) were obtained as disclosed on the last paragraph on page 6 of the originally specification. Further, Table III on page 11, Table IV on page 12 and Table V on page 13 each demonstrate the effectiveness of the various disclosed methods. Accordingly, the examples also provide the written description support of a method of ameliorating an erythrocyte sedimentation rate or C-reactive protein level consisting of identifying a patient, administering Epo to the patient, and identifying that the patient has an ameliorated erythrocyte sedimentation rate or C-reactive protein level. Therefore, methods of treatment are literally supported by the specification and one of ordinary skill in the art would recognize that such methods are disclosed for the treatment of all patients with rheumatoid arthritis.

19. In view of the above, it is my opinion that there is adequate support for claims 18, 20, 23-26, and 31-36 in the specification as filed, and thus, the new matter rejections should be removed.

Alan J. Howarth

Alan J. Howarth, Ph.D.

September 7, 2005

Date

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Comment

*247 FROM THE AMAZON TO THE ALPS: A COMPARISON OF THE PHARMACEUTICAL BIODIVERSITY LEGAL PROTECTION IN BRAZIL AND SWITZERLAND

Albena P. Petrova [FNa1]

*248 I. Introduction

In the aftermath of the 2002 Johannesburg World Summit on Sustainable Development, [FN1] countries around the world struggle to harmonize their national legislation [FN2] with Agenda *249 21 ("the Agenda"), [FN3] the Convention on Biological Diversity ("CBD"), [FN4] and the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS"). [FN5] Brazil is one such example where 20,000 medicinal plant samples disappear from the Brazilian rainforest every year due to the absence of permanent national legislation regulating access to medicinal herbs. [FN6] Bioprospecting [FN7] flourishes and professional scientists prefer not to conduct trials in Brazil, which delays the development of new drugs of global significance. [FN8] Thus, it is not a surprise that while Brazil owns about half of the world medicinal plant resources, *250 the country benefits the least from the commercial transformation of plants into pharmaceuticals. [FN9]

At the same time, Switzerland has twenty times fewer medicinal plants than Brazil, but benefits the most out of any country from the commercialization of plants. [FN10] Switzerland implemented guidelines for access to medicinal plant resources, [FN11] ecotourism, [FN12] and regulation of its endangered flora. [FN13] Switzerland also adopted the "Swiss claim" [FN14] in its patent *251 law, which is a claim for new therapeutic uses of known molecules, and continues to rely on ethnobiological knowledge. [FN15]

This comment compares the existing national laws for medicinal plant protection in Brazil and

Switzerland. It recommends that Brazil adopt the "Swiss claim" model for patent protection and make provisionary laws on access to genetic resources less stringent. [FN16] This comment further recommends that Brazil incorporate sustainable ecotourism guidelines into its draft law on access to genetic resources and introduce the red and blue book listing of endangered herbs. [FN17]
Part I presents the international legal framework for the protection of biodiversity and enforcement of intellectual property rights. [FN18] Part I also discusses the implementation of the relevant international treaties in Brazil and Switzerland. [FN19] Part II analyzes, first, why Brazil has much to learn from Switzerland and, second, what the basis for comparison is between the two countries. [FN20] Then, Part III recommends that Brazil adopt the type of intellectual property and environmental legal ***252** protection already in place in Switzerland. [FN21] Finally, the comment concludes in favor of the Swiss model for the protection of medicinal plant resources in Brazil. [FN22]

II. Background

This background section outlines the international framework for environmental protection of pharmaceutical biodiversity and its implementation in Brazil and Switzerland respectively. The section also describes TRIPS and its national implementation in each of the two countries.

A. Environmental Protection of Pharmaceutical Biodiversity

1. International Framework: Agenda 21 and CBD

Agenda 21 and the CBD contain provisions to assist countries in the implementation of national legislation against biopiracy. [FN23] The Agenda encourages commercial use of natural resources and the protection of ethnobiological traditional knowledge [FN24] through intellectual property. [FN25] It propagates a conservation of biological diversity and a sustainable use of biological resources. [FN26] The Agenda views biological resources as ***253** an important asset to yield sustainable benefits and emphasizes states' sovereign rights over their own natural resources. [FN27] Moreover, the Agenda recognizes that cooperation between scientists and industries could result in a transfer of technology to improve human health. [FN28]
The CBD calls for conservation and sustainable development of biodiversity, fair benefit-sharing, and absolute control of developing countries over their natural resources. [FN29] The ***254** CBD also recognizes the interest of developing countries in protecting their natural resources, the preservation of indigenous cultures, [FN30] and the transfer of technology. [FN31] The CBD addresses the importance of intellectual property rights to protect biodiversity in that proper intellectual property protection facilitates the transfer of technology and sharing of ethnobiological traditions. [FN32] In sum, the Agenda and CBD propagate access to genetic material against fair compensation and respect for ethnobiological knowledge.

2. National Implementation in Brazil

Although Brazil was the first country in the world to sign the CBD, [FN33] it has failed to update its law regulating access to biological diversity in compliance with the CBD and the Agenda. [FN34] The country has adopted various decrees, but lacks a permanent law regulating access to pharmaceutical biodiversity. In 1969, Brazil adopted a temporary decree that addressed access to biodiversity. [FN35] It established the Science Council, which is responsible for authorizing and supervising foreign scientific expeditions to explore the Amazon. [FN36] The Ministry of Science and Technology inspects and retains all materials collected by foreigners. [FN37] In 1990, Brazil implemented a decree ***255** that required an advance authorization to export biological material outside the territory of Brazil. [FN38]
In 1995, Brazil drafted a law that the Brazilian Senate has yet to ratify. [FN39] The Draft Law requires prior consent from the indigenous people over access to their territories and fair compensation for the utilization of genetic resources. [FN40] According to the Draft Law, Brazil has national sovereignty over its genetic resources [FN41] and the federal government has the sole authority to grant access to the country's medicinal plants. [FN42] The procedure to obtain permission is long and complex and requires detailed documentation. [FN43] The permission limits research ***256** activities to the geographic area and natural resources defined in the contract. [FN44] The petitioner, the government agency, the providers of traditional knowledge, and the other parties to the additional contracts negotiate mutually agreeable terms for the sharing of benefits. [FN45] A special fund from the collected money goes to the conservation, research, and inventory of genetic patrimony. [FN46] Access to genetic resources without authorization constitutes a crime subject to imprisonment and a fine of up to 10,000 times the daily fine. [FN47] Upon ratification, this law will control the access to biological material and its export abroad, as well as equitable remuneration.

[FN48]
The last piece of legislation concerning access to biological resources in Brazil is the Government Provisional Decree 2052. [FN49] The provisional decree constitutes the current Brazilian regime for access to genetic resources; [FN50] however, it still ***257** awaits discussions and approval by the Brazilian Congress. [FN51] The next subsection outlines the implementation of the Agenda and the CBD in Switzerland.

3. National Implementation in Switzerland

Unlike Brazil, Switzerland already had permanent laws for the protection of biodiversity [FN52] when it ratified the CBD in November 1994. [FN53] For example, the 1992 Swiss fund, endowed with fifty million Swiss Francs, contributed to the conservation of traditional landscapes and the preservation of cultural heritage. [FN54] Switzerland has also created "red lists" and "blue lists" of endangered plant species. [FN55] Red lists provide information about the endangered status of medicinal plants, determine what geographic sites need protection from access, and act as an important landscape, planning tool. [FN56] Blue lists register those red list species that increased in number and act as a psychological counterweight to the red lists. [FN57]

Switzerland also developed guidelines to serve as a reference for parties involved in the access to genetic resources and the sharing of benefits. [FN58] The country is presently implementing such national guidelines to regulate access to genetic resources, ***258** their utilization, and the fair sharing of benefits. [FN59] Switzerland presented those guidelines at the Johannesburg World Summit on Sustainable Development. [FN60] The following section discusses how commercial use of medicinal plants and equitable compensation in both Brazil and Switzerland is indispensable without national legislation compliant with the TRIPS Agreement.

B. Intellectual Property Law Protection of Biodiversity

1. The TRIPS Agreement

Similar to the CBD and the Agenda, TRIPS gives its member countries flexibility to choose the means to protect ethnobiological knowledge and medicinal plant resources. [FN61] The principal objective of TRIPS is to harmonize intellectual property laws around the world. [FN62] The agreement provides the minimum intellectual property standards for countries to implement in their national legislation. [FN63] TRIPS addresses intellectual property protection through patents. [FN64] The agreement ***259** allows member states to exclude from patent protection certain inventions. [FN65] For example, countries could deny patents for plants and animals other than microorganisms, but could not do so for non-biological and microbiological processes related to the production of plants. [FN66] Member states thus have flexibility to protect newly discovered medicinal herbs and traditional knowledge via patents. [FN67] However, the language of the agreement is ambiguous and controversial, [FN68] and it is presently undergoing a review by the TRIPS Council of the WTO. [FN69]

TRIPS fails to directly refer to the CBD and the Agenda or to prevent countries from regulating access to their genetic resources and from sharing the benefits from commercial use. [FN70] In addition, TRIPS lacks provisions on traditional knowledge but allows states to protect traditional knowledge by means ***260** other than patents. [FN71] Nevertheless, TRIPS seems consistent with the developmental purposes of Agenda 21 and the CBD. [FN72]

In sum, TRIPS has developmental, technological, and public purpose objectives. [FN73] However, its ambiguous language in regard to biotechnology patents complicates national implementation by member countries. [FN74] The following subsections discuss the implementation of TRIPS in Brazil and Switzerland in regard to pharmaceutical biodiversity.

2. TRIPS Implementation in Brazil

The new Industrial Property Law of Brazil [FN75] came into effect in April 1996 to comply with the minimum requirements established by the TRIPS Agreement. [FN76] The law appears, however, to have weaknesses, [FN77] specifically live organisms are not discoveries and therefore are not patentable. [FN78] The Industrial Property Law of Brazil states an invention is patentable if it meets the requirements of novelty, inventive step, and industrial application. [FN79] In other words, discoveries do not constitute inventions, [FN80] and patents are granted neither to biological materials found in or isolated from nature nor to second medical ***261** uses. [FN81] Thus, the new industrial law of Brazil does not allow patents for biological materials isolated from nature and for natural biological processes. [FN82] Allowing patents for isolated biological matter and secondary use in Brazil could attract more foreign investment and stimulate development of modern biotechnology. [FN83]

3. TRIPS Implementation in Switzerland

Switzerland adopted its new intellectual property law in 1996. [FN84] According to the new law, inventions contrary to public policy cannot obtain a patent. [FN85] The Swiss Patent Office grants patents for microbiological and non-biological processes, [FN86] but the Swiss patent law provides no explicit language about biological extractions. [FN87] Switzerland has recognized a "**'Swiss type' claims** . . . for new therapeutic uses of known molecules . . . ." [FN88] Therefore, if a known substance has new medicinal uses, such ***262** inventions qualify for patent protection. [FN89] For example, aspirin's original use was to treat headaches. [FN90] Later on, it became known that aspirin could also treat heart diseases, and therefore patents could protect this second medical use to stimulate future pharmaceutical research. [FN91]

The "Swiss claim" approach is an important aspect of the Swiss patent law because it facilitates the development of plant-derived drugs based on traditional ethnobiological knowledge, [FN92] and therefore a similar approach could benefit Brazil. Patents for non-biological processes and secondary use benefit the protection of pharmaceutical biodiversity and yield commercial benefits for the country that has implemented them. [FN93] The following analysis will establish the framework for comparison between the two countries.

III. Analysis

Given that the international framework provides only minimal standards for protection of pharmaceutical biodiversity, this analysis section considers constitutional protection, richness of pharmaceutical biodiversity, and ethnobiological traditions in Brazil and Switzerland. While Brazil is a heaven of pharmaceutical biodiversity, its stringent temporary laws act as a barrier to the progress of science, and the country's present patent protection hinders innovation.

***263** A. The International Framework Only Sets Minimal Standards

The Agenda, CBD, and TRIPS only provide the minimum international framework for protection of biodiversity through intellectual property, and they all require language clarification. [FN94] For example, the Agenda and CBD fail to specify how benefit sharing could take place, except that negotiating parties must reach a mutual agreement. [FN95] The Agenda and CBD also fail to explicitly refer to TRIPS [FN96] and remain silent on the issue of patentable subject matter. [FN97]

TRIPS creates a discord between developed and developing countries over the criteria for patentability in the field of biotechnology and the relationship between TRIPS and CBD. [FN98] Developed countries support a strong protection of all biotechnological innovations through patents. [FN99] Developing countries, at the same time, accuse TRIPS of encouraging biopiracy and environmental damage by allowing for patenting of biological and non-biological processes. [FN100] Adequate patent protection for biological extracts and processes, however, fosters economic ***264** growth and development and inflow of foreign investment. [FN101] It is therefore in the best interest of developing countries, like Brazil, to adopt the developed countries' viewpoint, such as the Swiss model, to recognize the importance of patent protection for the biotechnology industry. [FN102] The following section considers the basis for comparison between Switzerland and Brazil.

B. Why the Swiss Model is Adaptable in Brazil

1. Constitutional Protection of Biodiversity

Brazil and Switzerland have incorporated the protection of the environment in their constitutions. [FN103] Both countries' constitutions provide that a well-maintained environment is essential for a healthy way of life, [FN104] and that the government and the community have the duty to protect the environment. [FN105] Also, the two countries' constitutions forbid the use of gene ***265** methods that endanger human life. [FN106] Similarly, each protects flora from extinction, [FN107] along with nature and cultural heritage. [FN108] The Brazilian and Swiss constitutions show concern about access to and utilization of natural resources. [FN109] The constitutions of Brazil and Switzerland thus illustrate their effort to preserve nature for future generations. [FN110]

2. Richness of Pharmaceutical Biodiversity

In addition to constitutional similarities, both countries enjoy rich pharmaceutical biodiversity. [FN111] Switzerland is the home of the Swiss Alps, which are rich with conifer forests and medicinal plants such as oleader, palm trees, and mimosa. [FN112] Europeans widely believe that "[i]f mountains had a home, it would be Switzerland." [FN113] Switzerland is one of the countries ***266** with the highest biodiversity in Europe. [FN114] Switzerland's biodiversity protection is exemplary because the country has implemented restrictive laws and the Swiss deeply care about their country's

natural resources. [FN115] The Alps are among the few large wildlife areas within Europe that continue to stay untouched by industrial development. [FN116]
Brazil also possesses some of the most diverse and rich ecosystems in the world. [FN117] The Brazilian Amazon rainforest occupies eighty percent of the South American Amazon and comprises sixty-seven percent of the world's tropical forests. [FN118] The Brazilian Amazon includes twenty-two percent of the known plant species in the world [FN119] and fifty percent of the world's biodiversity. [FN120] Unlike Switzerland, Brazil has serious conservation problems. The Brazilian Amazon rainforest suffers from ecological destruction. [FN121]
***267** In 2000, the Brazilian Amazon was 7,037 square miles and by 2001, logging and fires destroyed 6,095 square miles. [FN122] Furthermore, a government development plan, including infrastructure projects, could destroy forty-two percent of the Amazon if it progresses as promised. [FN123] While, both Switzerland and Brazil are rich in medicinal plant resources, biopiracy in Brazil is flourishing at a large scale and resources leave the country without compensation because of the lack of permanent law on access to genetic resources. [FN124]
3. Ethnobiological Traditions
Wild medicinal plants are an important source of medicines for eighty percent of the developing world. [FN125] By consulting traditional medicinal knowledge, researchers for new medicinal drugs can increase the success ratio in drug trials from one success in ten thousand samples to one success in two samples. [FN126] Switzerland is one such country that has solid historical traditions in ethnobiological medicine. [FN127]
***268** The field of medicinal chemistry and the use of medicinal plants originated in Switzerland. [FN128] In Switzerland, medicinal plants serve as traditional medicines, herbal teas, health foods, and pharmaceuticals. [FN129] For instance, Adonis vernalis is a plant with well-known medicinal properties, [FN130] thyme cures dry spasmodic coughs and bronchitis, [FN131] and horehound treats respiratory problems and helps remove phlegm from the lung. [FN132]
Brazil is also well-known for its ethnobiological traditions. [FN133] Many of its plants find medicinal and cosmetic uses based on ethnobiological knowledge. [FN134] For example, the British Body Shop uses oil extracted by the Calapo Indians [FN135] to make skin cream and shampoos, [FN136] Aveda produces cosmetics using the urucum plant, which is a vegetable bleach, [FN137] and Channel No. 5 uses the pau-rosa. [FN138] An American ethnobiologist ***269** exclaimed that "[e]very time a shaman dies, it is as if a library burned down." [FN139]
In sum, Switzerland and Brazil extensively use ethnobiological knowledge in their pharmaceutical and medical industry: another reason why the Swiss model would be relevant in Brazil. The next section discusses Brazil's rich ethnobiological traditions and biodiversity and its failure to yield enough benefits from the commercialization of its medicinal plants resources.

C. Brazil: Rich in Biodiversity, but Poor Commercialization
1. A Heaven of Pharmaceutical Biodiversity
Statistics demonstrate that Brazil has the highest number of plant species in the world, while its per capita income is one of the lowest. [FN140] Brazil's biodiversity serves as a rich source for plant-derived drugs. [FN141] For instance, salegen, a medicine used to treat xerostoma, contains active ingredients extracted from a plant native to Northeastern Brazil that tribes have used for generations. [FN142] Additionally, Brazilian found quebra-pedra is an herb that treats hepatitis, and natural prozac, another Brazilian found herb, is the main ingredient in the medicine prozac. [FN143]
However, at the same time, Brazil receives no compensation for the utilization of the natural resources. [FN144] The ***270** rainforest is worth $43 billion for plant-derived medicines [FN145] and Brazil receives less than one percent of the accrued benefits from commercialization. [FN146] The main reason for the flourishing biopiracy and bioprospecting in Brazil is the lack of adopted permanent law on access to biodiversity. [FN147]
In addition, dialogue among foreign scientific and business communities and the Brazilian government is strained. [FN148] Biotechnology is not part of the government's agenda, and this has had devastating consequences for the country's economic development. [FN149] Foreign pharmaceutical companies and researchers state that the lack of permanent laws decrease their interest in working in Brazil. [FN150] Many companies have postponed their activities until the implementation of a permanent law regulating access to pharmaceutical biodiversity. [FN151] For example, under an agreement signed between Novartis and BioAmazonia in 1999, Novartis promised to spend $4 million in research programs in the region. [FN152] In return, BioAmazonia allowed Novartis ***271** to ship 10,000 gene samples to Switzerland. [FN153] However, BioAmazonia revoked the agreement,

accused Novartis of biopiracy, and cancelled the contract. [FN154] Novartis stated its intent to no longer develop projects in Brazil because the country lacks permanent laws regulating access to pharmaceutical biodiversity and the Brazilian government fails to enforce its contractual obligations. [FN155] Thus, the lack of permanent laws on access to biological resources and the inability to enforce contracts create a disincentive among foreign companies to explore Brazil's rich pharmaceutical biodiversity for new medicinal drug development. [FN156] This is detrimental to Brazil because the country lacks enough researchers and national infrastructure to benefit from commercial uses of its biodiversity. [FN157]

2. A Barrier to Progress of Science

The provisional decree in Brazil hinders international scientists from exploring the rainforest and researching medicinal plants for new drug development. [FN158] Research permits and access and research restrictions cause scientists to reconsider ***272** work in the Amazon forest and to leave thousands of plants unknown and unused for potentially vital medicines to cure such diseases as HIV/AIDS. [FN159] The problem is significant when researchers in other countries need samples of natural plants to work on their doctoral dissertations and lack permission to ship plant samples to their laboratories. [FN160]

Moreover, nationalist movements in Brazil hinder the access of international scientists to the rainforest. [FN161] The Brazilian military demarcates indigenous areas to protect the rainforest from foreign invasion, which is disastrous for researchers who collect samples and search for unknown plants with rare medicinal value. [FN162] The increased number of criminal charges against foreign scientists also creates a disincentive among foreign scientists to participate in research expeditions in the Amazon rainforest. [FN163] Harsh visa restrictions, nationalist tension, and severe criminal penalties in Brazil act as serious barriers for world renown scientists to undertake research ***273** missions that could lead to the discovery of new drugs of global significance. [FN164]

3. Present Patent Protection in Brazil Hinders Innovation

Current Brazilian patent law eliminates the possibility of patenting products extracted from medicinal plants, and, until recently, the law excluded biological processes from patents. [FN165] Moreover, Brazil invests only 1.24 percent of its GDP in science and 0.7 percent goes to Research and Development, and additionally the Ministry of Science and Education only dates back to 1985. [FN166] This is problematic because the biotechnology industry depends on patent law protection due to the high costs of research, development, and commercialization. [FN167] For example, it costs about $231 million to develop a drug, and patenting a biological invention in the United States costs approximately $80,000. [FN168] Consequently, pharmaceutical research and development takes place predominantly in countries with a strong research and development sector such as Switzerland. [FN169]

Economic studies on patents concluded that intellectual property protection is crucial for foreign direct investment and ***274** development. [FN170] About eighty percent of the firms in the study testified that strong patent protection is important for investment in research and development in developing countries, and that Brazil has weak patent protection. [FN171] Furthermore, biotechnology is an industry in which wealth depends on patents. [FN172]

Allowing patents for natural extracts from medicinal plants would accrue more local benefits to Brazil. [FN173] The country should view its genetic resources as a common heritage of mankind that could be a significant resource to produce life-saving, plant-derived medicines for the benefit of the entire world. [FN174] After all, since the Swiss model is relevant in Brazil, the Amazon country may refer to it for guidance on how to effectively protect its pharmaceutical biodiversity.

IV. Recommendations

This Part recommends that Brazil increase access of international scientists to its medicinal plants and regulate ecotourism, ***275** adopt the "Swiss claim" patents, and incorporate the listing of endangered herbs.

A. Make Medicinal Plants More Accessible to Scientists and Regulate Ecotourism

The Brazilian law on access to genetic resources limits the access of international scientists to medicinal plants in the Amazon jungle. [FN175] As a result of the long process to obtain a scientific permit in order to access the resources and the criminal penalties, scientists prefer not to conduct research in the Brazilian forests. [FN176] Brazil should still continue to control access to its resources and their commercialization; however, the country's Draft Law should introduce less cumbersome restrictions. [FN177] The Draft Law should reduce the wait period to obtain a permit to less than one

year, and it should allow scientists to keep the collected samples against fair compensation. [FN178] The Draft Law should take into account the Swiss guidelines for access to biological material. [FN179] The Brazilian Draft Law should incorporate the following provisions from the Draft Guidelines of Switzerland. [FN180] The law should implement an objective access to the country's medicinal plant resources to reassure researchers that their rejection to Brazil's genetic resources is not discriminatory and arbitrary. [FN181] In addition, Brazil should remove the requirement to perform research and development in Brazil because pharmaceutical companies generally keep their know-how in their headquarters in order to protect their intellectual property assets from appropriation ***276** abroad. [FN182] Decisions about access to the genetic resources could result in twenty days because if it takes too long, as in Brazil, researchers could change their dissertation topics and conduct research in countries that offer more speedy access to genetic resources. [FN183] Sharing of intellectual property assets should be permissive because otherwise pharmaceutical companies would be skeptical about investing in the Brazilian Amazon. [FN184] In addition, a mediator should resolve differences and help avoid biased Brazilian courts. [FN185]

Furthermore, ecotourism should become part of the Draft Law before Brazil increases its use. [FN186] The Brazilian government has already drafted guidelines for a national ecotourism policy and Brazil has a vast heritage for ecotourism. [FN187] The guidelines should require, as the Swiss policy, an environmental assessment before the access to the natural resources takes place and should become part of the Draft Law for access to genetic material. [FN188] Researchers entering Brazil under the Draft Law should be required to comply with environmentally sound methods for access to the medicinal plant resources. [FN189] This is especially important because presently foreign tourists use ecotourism to obtain access to Brazil's medicinal plants for bioprospecting purposes. [FN190]

***277** Ecotourism finds wide uses in Switzerland and people are becoming increasingly aware of the need to preserve the natural and cultural landscape. [FN191] For example, the Swiss Confederation has limited transportation to certain tourism areas to protect the natural resources and new projects for transport access are subject to environmental impact assessment. [FN192] It has also issued guidelines for managing conflicts between tourism and biological diversity. [FN193] Switzerland urges tourists to contribute to the survival of ecosystems, respect human dignity, choose sustainable mobility, and participate in civil society during their travel. [FN194]

Similar to Switzerland, Brazil should make its proposed Draft Law less restrictive and more aware of ecotourism. [FN195] This would likely assist Brazil to attract more internationally renown scientists and accrue benefits from commercialization. The next section discusses how it would be advantageous to Brazil to grant patent protection to secondary uses.

B. Protect Biodiversity Through the "Swiss claim" Patent Approach

Brazil would protect its medicinal plants and stimulate pharmaceutical companies to research for new medicinal uses of already discovered drugs if it adopts the "Swiss claim" approach as Switzerland. [FN196] As a result, Brazilian and foreign ***278** pharmaceutical companies would have an incentive to search for secondary cures from already discovered and patented drugs. [FN197] This would also encourage clinical research and new uses in Brazil for traditional medicines. [FN198] For instance, "Swiss claim" patents in Switzerland have increased the research and development of biotechnology companies in biotechnology investment. [FN199] The "Swiss claim" type could possibly discover several uses in just one medicinal plant in Brazil and save time for scientists in terms of searching for new medicinal plants for genetic material. [FN200] Otherwise, investment in new pharmaceutical research would further diminish because without patent protection for secondary uses, researchers have little incentive to investigate the properties of existing pharmaceuticals in order to determine any unknown medical uses. [FN201] The "Swiss claim" approach could therefore benefit the medicinal plant protection and drug development in Brazil. [FN202]

***279** C. Red and Blue List the Endangered Herbs in the New Database

Brazil should regulate access to endangered herbs as is the practice in Switzerland. [FN203] "Red lists" provide information about the endangered status of Swiss medicinal plants and landscape planning. [FN204] In addition, "blue lists" complement the red lists to monitor stabilization and increase of plant resources. [FN205] The use of red lists and blue lists has been especially successful in northern Switzerland, where red list findings tended to depress people, while blue lists encouraged decision-makers and the public to increase their nature conservation efforts. [FN206]

Brazil recently has created a centralized databank to store knowledge accumulated by local indigenous people. [FN207] This collection of traditional knowledge and medicinal plants would

provide information to patent offices about prior art [FN208] and would be helpful for sharing the benefits between indigenous people and scientists. [FN209] Brazil has already mapped three hundred medicinal plant species. [FN210] A red list specification of ***280** plants in the Brazilian database would enable the government of Brazil to stay abreast of what species are decreasing in numbers. [FN211] In addition, use of blue lists should help maintain nature conservation efforts as in Switzerland. [FN212] Consequently, the Brazilian government should regulate shipping of samples abroad, determine access to the Amazon rainforest, and monitor landscape planning. [FN213]

V. Conclusion

Brazil is a haven of pharmaceutical biodiversity, but its lack of permanent legislation on access to medicinal plants acts as a barrier to progress of international science, and its present patent law hinders innovation. [FN214] Instead, Brazil could attract foreign scientists by adapting its Draft Law to the Swiss guidelines for access to biological resources and by passing a permanent law on access to genetic resources that is fair to foreign researchers. [FN215] Brazil should provide patent protection for secondary uses of already patented plant-derived medicines to encourage the continuance of trials on already patented medicines. [FN216] Since ecotourism could be an easy excuse for biopiracy, the Brazilian government should also consider including ecotourism in its Draft Law on access to biological resources. [FN217] Finally, the Swiss method of red and blue listing would be a good addition to the recently created Brazilian databank system to keep track of endangered medicinal plants in the Amazon. [FN218]

***281** Brazil has much to learn from Switzerland since the two countries share significant similarities in their constitutional protection of biodiversity, richness of medicinal plants, and ethnobiological traditions. [FN219] The Swiss model should assist Brazil in protecting medicinal plant resources and managing plants' commercial use in a way that would return economic benefit to Brazil. [FN220]

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[FN1]. See World Summit on Sustainable Development, at http://www.johannesburgsummit.org/html/basic_info?basicinfo.html (last visited Aug. 10, 2002) (reporting that the Johannesburg Summit took place from August 26 to September 4, 2002, and focused on conservation of natural resources). See also Paula Stober, Summit Holds Hope for Saving the Planet, News & Record, Aug. 6, 2002, at A10 (mentioning that the 2002 World Summit evaluated developments since the 1992 Rio Earth Summit), LEXIS, News Group File; Michael Hanlon, Commentary, Daily Mail, Aug. 7, 2002 (suggesting that the 1992 Earth Summit only resulted in political debates and that biodiversity today is decreasing at a faster rate than ten years ago), LEXIS, News Group File; James Lamont & John Mason, A Long Way to Go for a Little Success, Fin. times (London), Sept. 4, 2002 (noting that the summit only achieved a limited success in the area of biodiversity protection), LEXIS, News Group File. See generally Barry James, Summit Aims, Again, for a Better World; Lofty Goals, Sorry Record, Int'l Herald Trib., Aug. 8, 2002, at 1 (expressing an opinion that the results since the 1992 Earth Summit are disappointing and that environmental degradation nowadays is much worse than ten years ago), LEXIS, News Group File.

[FN2]. See Mario Osava, Environment-Brazil: From Pariah to World Conservation Leader, Inter Press Service, June 6, 2002 (explaining that Brazil seeks to reinforce its leadership in the area of biodiversity and to stay behind the commitments it made ten years ago in Rio de Janeiro), LEXIS, News Group File. See also S. K. Verma, Biodiversity and Intellectual Property Rights, CASRIP Newsletter (University of Washington School of Law/CASRIP, Seattle, WA), Spring 2000, at 1-2 (declaring that all members of the CBD and TRIPS face the problem of compliance), at http://www.law.washington.edu/casrip/newsletter/newsv7i2Verma.pdf (last visited Aug. 7, 2002).

[FN3]. See U.N. Conference on Environment and Development, Agenda 21, U.N. Doc. A/Conf.151/26/Rev.1 (1992) (noting the importance of environmental conservation and the role of

indigenous people for sustainable development), at http://www.un.org/esa/sustdev/agenda21.htm (last visited Aug. 7, 2002).

[FN4]. See U.N. Convention on Biological Diversity, June 5, 1992, U.N. Doc. DPI/1307 (1992) [hereinafter CBD] (emphasizing the ownership of every country over its own natural resources and the importance of intellectual property law to preserve natural resources), at http:// www.biodiv.org/convention/articles.asp (last visited Aug. 6, 2002). See generally Carrie Smith, Patenting Life: The Potential and the Pitfalls of Using the WTO to Globalize Intellectual Property Rights, 26 N.C.J. Int'l L. & Com. Reg. 143, 152 (2000) (providing an analytical overview of the CBD such as seen by developed and developing countries).

[FN5]. See Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 33 I.L.M. 1197 (1994) [hereinafter TRIPS] (defining the minimal standards of intellectual property protection).

[FN6]. See Embassy of Brazil, Sustainable Amazon, Summer 2000 (assessing that every year 20,000 extracts leave Brazil), at http:// www.brasilemb.org/environ_sustainable_amazon.shtml (last visited Aug. 7, 2002).

[FN7]. See Valentina Tejera, Tripping Over Property Rights: Is it Possible to Reconcile the Convention on Biological Diversity with Article 27 of the TRIPS Agreement, 33 New Eng. L. Rev. 967, 971 (1999) (defining biodiversity as a search by professional botanists and shamans for biological resources for pharmaceutical use, or a "gene hunting," that results in treatments for diseases such as cancer).

[FN8]. See Ministry of the Environment, First National Report for the Convention on Biological Diversity-Brazil 159 (1999) [hereinafter First National Report of Brazil] (revealing that the main reason for biopiracy in Brazil is the lack of permanent law on access to genetic resources and benefit-sharing), available at www.biodiv.org/doc/world/br/br-nr-01-p9-en.pdf (last visited Aug. 9, 2002). See also Estela Viana, Brazil's Biodiversity Attracts More Interest, Gazeta Mercantil, June 1, 2001 (explaining that the fauna and flora in Brazil may be worth $4 trillion), LEXIS, Major World Newspapers.

[FN9]. See Ana Paula Corazza, Bio Plunderers, Brazil, Mar. 2001, (specifying that of the 240,000 species of plants with flowers in the world, 150,000 are in the tropics, and of these, 55,000 are on the territory of Brazil), at http:// www.brazzil.com/p24mar01.htm (last visited Aug. 10, 2002). See also Larry Rohter, Brazil's Tribes Seek Jungle-Plant Profits, Pittsburgh Post-Gazette, Dec. 31, 2001 (stating that many of those plants grow only in Brazil and indigenous people have used them to treat various diseases), 2001 WL 28685712; First National Report of Brazil, supra note 8, at 12 (declaring that Brazil is the richest megadiversity country and has about twenty-two percent of the world's plants). See generally Embassy of Brazil, Key Facts 1 (providing statistics about Brazil's investment in scientific research and development), at www.brasilemb.org/tech2.shtml (last visited Aug. 6, 2002).

[FN10]. See A. Cunningham, Ethics, Biodiversity, and New Natural Products Development, People and Plants Online (Apr. 1993) (comparing biodiverse countries with countries that benefit the most from the commercialization of their natural resources), available at http:// www.rbgkew.org.uk/peopleplants/dp/dp2 (last visited Aug. 7, 2002).

[FN11]. See Draft Guidelines of Switzerland on Access and Benefit Sharing Regarding the Utilization of Genetic Resources, Oct. 30- Nov. 1, 2000 [hereinafter Swiss Guidelines] (outlining important measures to ensure the proper preservation and access to natural resources), at http:// www.unctad.org/trade_env/docs/swiss.pdf (last visited Aug. 7, 2002).

[FN12]. See D. J. De Villier, Beyond Attractive Destinations, World Surface.com (July 30, 2001) (defining ecotourism as a type of tourism where tourists visit places and pay special attention to the preservation of the environment, and stating that it is a powerful source for creating more jobs, combating poverty, and protecting the natural and cultural environment), at http://www.worldsurface.com/browse/static.asp?staticpageid=1084 (last visited Aug. 10, 2002).

[FN13]. See Swiss Agency for the Environment, Forests and Landscape, Swiss Clearing-House Mechanism Biodiversity: Switzerland at a Glance/ Red Lists/ Introduction (1998) (describing the purpose and impact of the red lists of endangered plant species), available at http:// www.buwal.ch/nachh/chm/e/ch/problems/redintro.htm (last visited Aug. 10, 2002).

[FN14]. See Loi fédérale du 25 juin 1954 sur les brevets d'invention, Legge federale del 25 giugno 1954 sui brevetti d'invenzione, Bundesgesetz vom 25. Juni 1954 über die erfindungspatente [Switzerland Federal Law on Patents for Inventions], RO 1955 893, RU 1955 899, AS 1955 871, art. 7 (c) (1954) (amended 1995) ([redacted]), available at http://clea.wipo.int/clea/lpext.dll?f=templates&fn=main-hit-h.htm&2.0 (last visited Aug. 10, 2002).

[FN15]. See Gelvina Stevenson, Trade Secrets: The Secret to Protecting Indigenous Ethnobiological (Medicinal) Knowledge, 32 N.Y.U. J. Int'l & Pol. 1119, 1132 (2000) (defining ethnobiological knowledge as knowledge belonging to indigenous people, where indigenous people can draw attention to a specific plant, describe the specific part of the plant that contains the medical substance, identify the time of the year when the substance is present, explain the physiological effects of that plant, describe the method of preparing the substance, and thus provide valuable clues to the identity of active molecules and expedite their isolation in the laboratory).

[FN16]. See infra notes 173-84, 194-200 and accompanying text (recommending that Brazil make its medicinal plants more accessible to scientists and adopt the "Swiss claim" approach).

[FN17]. See infra notes 184-93, 201-11 and accompanying text (discussing that Brazil should incorporate ecotourism guidelines into its draft law and that red-listing should be a good approach).

[FN18]. See infra notes 23-32, 60-73 and accompanying text (outlining the international laws for the protection of biodiversity and intellectual property).

[FN19]. See infra notes 33-59, 74-91 and accompanying text (describing how Brazil and Switzerland implemented the international laws on biodiversity and intellectual property protection into their national legislation).

[FN20]. See infra notes 101-37 and accompanying text (comparing the constitutional and ethnobiological traditions in Brazil and Switzerland).

[FN21]. See infra notes 173-211 and accompanying text (suggesting that Brazil make its biodiversity legislation less stringent, adopt the "Swiss claim" patents and implement the red listing system).

[FN22]. See infra notes 212-18 and accompanying text (concluding favorably on the implementation of the Swiss model in Brazil).

[FN23]. See Graham Dutfield, Developing and Implementing Systems for Protecting Traditional Knowledge: A Review of Experiences in Selected Developing Countries, at 8 (defining biopiracy as an unauthorized extraction of biological resources or associated biological knowledge from developing countries), available at http://www.unctad.org/trade_env/tk.htm (last visited Aug. 10, 2002). See also Michael Gollin & Sarah Laird, Global Policies, Local Actions: The Role of National Legislation in Sustainable Biodiversity Prospecting, 2 B.U. J. Sci. & Tech. L. 16, para. 15 (1996) (highlighting that the best and only possible way to deal with global problems is through adequate laws and regulations).

[FN24]. See CBD, supra note 4 (defining traditional knowledge as "knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles" in article 8(j)). Id.

[FN25]. See David R. Downes, How Intellectual Property Could be a Tool to Protect Traditional Knowledge, 25 Colum. J. Envtl. L. 253, 281 (2000) (concluding that intellectual property use in

accordance to the development needs of developing countries could protect their biological knowledge).

[FN26]. See Agenda 21, supra note 3, ch. 15 (stating that the natural ecosystems contain most of Earth's biodiversity and that biological resources provide medicines, and that the current decline in biodiversity is a serious threat to human development). See also id. ch. 2 (noting that environment and trade policies should be mutually supportive and that governments should meet those objectives through multilateral forums).

[FN27]. See id. ch. 15 (highlighting that developing countries have control over their biological resources and must benefit from the biotechnological development and commercial utilization of the products derived from their national resources, and that those goals could be achieved through a broader regional and international cooperation). See also id. ch. 26 (clarifying that governments around the world should incorporate the rights and responsibilities of indigenous people in their national legislation); Tanja Sturm, Government Launches Bid to Discover New Herbal Medicine, World Markets Research Centre, Feb. 26, 2002 (observing that the World Health Organization states there are 250,000 species of medicinal plants in the developing world and that those plants' extracts are the source of "more than eighty-five percent of the medicines used by eighty percent of the population in the developing world"), LEXIS, Major World Newspapers.

[FN28]. See Agenda 21, supra note 3, ch. 16 (stating the necessity for training and technology transfer in the developing world).

[FN29]. See Press Release, U. N. Convention on Biological Diversity, International Day for Biological Diversity Dedicated to Forest Biodiversity (May 22, 2002) (declaring that forests are vital for human health and other economic benefits), at www.biodiv.org/doc/press/pr-2002-05-02-ibd-en.pdf (last visited Aug. 5, 2002). See also U.N. Conference for Trade and Development, The Biotrade Initiative (highlighting that the world production of natural ingredients for cosmetics has been estimated at $1 billion, out of which fifty-five percent is derived from developing countries, and that ecotourism is becoming important within the tourism industry generating more than $260 billion per year), at http://www.biotrade.org/QuickPlace/biotrade/Main.nsf/h_B4BD9585D70EA32CC1256C0000352A94/5d978e894aaaa092c1256c0000352aba/! OpenDocument (last visited Aug. 10, 2002); CBD, supra note 4, art. 1 (establishing that the objectives of the CBD are the conservation of biological diversity, the sustainable use of its components, and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources); Id. art. 15 (declaring the importance of sharing the benefits from the commercial utilization of genetic resources); Vandana Date, Global "Development" and the Environmental Ramifications- The Interlinking of Ecologically Sustainable Development and Intellectual Property Rights, 27 Golden Gate U.L. Rev. 631, 631 (1997) (describing the link between biodiversity and intellectual property rights in the CBD). See generally Amy Guerin Thompson, An Untapped Resource in Addressing Emerging Infectious Diseases: Traditional Healers, 6 Ind. J. Global Leg. Stud. 257, 272 (1998) (noting that traditional medicine is vital to fight the spread of infectious diseases).

[FN30]. See CBD, supra note 4, art. 8(j) (stating the importance of indigenous people and their cultures for sustainable development).

[FN31]. See id. art. 16 (stating that access and transfer of environmentally sound technology among contracting parties are essential for the conservation and sustainable use of biological diversity); Id. arts. 20- 21 (remarking that developed countries shall provide financial resources to enable developing countries to meet the costs of implementation of the CBD).

[FN32]. See CBD, supra note 4, arts. 15-16, 19 (addressing respectively the issue of access to genetic resources, the access and transfer to technology, and the handling and distribution of benefits to developing countries).

[FN33]. See First National Report of Brazil, supra note 8, at 159 (stating that Brazil signed the Convention on Biological Diversity during the United Nations Conference on Environment and Development in Rio de Janeiro in June 1992).

[FN34]. See id. (discussing Decree No.65.057 from August 26, 1969 as it relates to access to genetic material in Brazil).

[FN35]. See id.

[FN36]. See id. (stating that the decree No. 65.057 from August 1969 established the norms for scientific expeditions in Brazil).

[FN37]. See id. (reporting that collected materials include pressings, photographs, and drawings of the scientific material).

[FN38]. See id. at 158 (discussing that decree No. 98,830 from January 15, 1990, legislates on the collection of scientific material by foreigners).

[FN39]. See First National Report of Brazil, supra note 8, at 159 (discussing that Bill of Law No. 306/95 still has not become a permanent law). See also Brazil Sees Promise in Jungle Plants, But Tribes See Peril, Dec. 23, 2001 (discussing that since permanent legislation is absent, the Brazilian government has issued several temporary decrees to regulate research, and remarking that in the absence of permanent legislation, many foreign research institutions hesitate to sign cooperation contracts, especially after a contract between a government-controlled institution and the pharmaceutical company Novartis failed in 2000), at http://senrs.com/brazil_sees_promise_in_jungle_plants.htm (last visited Aug. 5, 2002); Greg Brown, Holding Pattern, LatinTrade.com, Health & Medicine Section, (Nov. 2001) (discussing a deal with Novartis in which they were to spend 4 million on research programs in Brazil and in return they would be permitted to ship 10,000 gene samples to its Basel headquarters; however, the contract was later denounced and Novartis was accussed of biopiracy), at http:// www.latintrade.com/newsite/content/archives.cfm?TopicID=13&StoryID=1493 (last visited June 14, 2002).

[FN40]. See Brazil's Bill on "Access to Genetic Resources," Decreto No. 306 de 19.09.1995, art. 5 (Nov. 19, 1997) (trans. By Vanira Tavares) (outlining provisions for access to genetic resources and their derived products), at http://ibaecology.gsfc.nasa.gov/ibaeco/Invest/docs/genetic_resources_bill.htm (last visited June 22, 2002).

[FN41]. See id. ch. III, art. 5(II) (recognizing the national sovereignty of Brazil over their genetic resources and derived products on its territory).

[FN42]. See id. Title IV, ch. I, art. 14 (stating that access to genetic resources in Brazil shall be subject to prior government authorization and to the signing of a contract between the government and the foreign object, and establishing that the government of Brazil must keep a reference file of the contract negotiations).

[FN43]. See id. Title IV, ch. I, sec. I, art. 15 (outlining that, "to obtain authorization and sign a contract of access to a genetic resource, the petitioner or the agency of access must present a detailed petition, together with the project of access," as well as "complete information on the timetable, budget, and sources of financing for the activities," detailed and specific description of the genetic resources to which access is intended, their current and potential uses and detailed description of the collection systems and tools to be used, precise location of the areas where the procedures of access will be carried on, and an indication of the destination of the material collected and of its probable future use).

[FN44]. See id. Title IV, ch. I, sec. V, art. 34 (noting that the government must monitor "compliance with the provisions of the authorization and of the contract of access" and ensure a detailed account of the activities, and a detailed destination of the collected samples).

[FN45]. See id. Title IV, ch. I, sec. VI, art. 35 (reporting that in addition to the payments and sharing of benefits agreement, the government must ensure a fair compensation in the form of money or

commercialization rights as described in the contract of access).

[FN46]. See Brazil's Bill on Access to Genetic Resources, Decreto No. 306 de 19.09.1995, supra note 39, art. 36 (stipulating that the forms of compensation shall form a special fund for the conservation, research, and inventory of the biological resources to support projects related to the conservation of natural resources).

[FN47]. See id. Title IV, ch. I, sec. VI, art. 56 (acknowledging that "the acquisition and commercialization of genetic resources and derived products," their shipment abroad, and the use of traditional knowledge without an authorization constitute a crime subject to imprisonment of one to four years and a fine of up to ten thousand Brazilian currency money).

[FN48]. See First National Report of Brazil, supra note 8, at 159-60 (explaining that once the Draft law is passed, it will apply to biological and genetic resources in Brazil and the government will have the right to prohibit access to endangered species).

[FN49]. See Francisco Arcanjo, Intellectual Property Rights and Biodiversity in Brazil: Conservation, Sustainable Use and Protection of the Indigenous Rights, 36-40 (Nov. 2000) (comparing the provisional decree with the Senate bill 306/95 and stating that the provisional decree bears the same idea as the Senate bill and has the force of a law), at http://www.gwu.edu/~ibi/minerva/fall2000/Eugenio.Arcanjo.pdf (last visited Aug. 6, 2002).

[FN50]. See id. at 36 (asserting that the provisional decree is the current decree for access to natural resources in Brazil until the Brazilian Senate passes a permanent law).

[FN51]. See id. (arguing that a law becomes permanent in Brazil after an approval by the Brazilian Senate).

[FN52]. See Swiss Agency for the Environment, Forests and Landscape, National Report of Switzerland for the Convention on Biological Diversity, 15 (1998) [hereinafter National Report of Switzerland] (stating that the pre-existing laws include the Federal Law on the Protection of Nature and the Landscape from 1966, the Federal Law Relating to the Protection of the Environment from 1983, and the Federal Law on Forests from 1991), at http:// www.biodiv.org/doc/world/ch/ch-nr-oi-en.pdf (last visited Aug. 5, 2002).

[FN53]. See id. (describing the progress made in Switzerland to implement the CBD in the country's national legislation).

[FN54]. See id. at 17 (stating that the fund commemorated the 700th anniversary of the Swiss Confederation).

[FN55]. See id. at 18 (describing the various methods introduced in Switzerland to protect endangered species and threatened biodiversity systems).

[FN56]. See Swiss Clearing House Mechanism Biodiversity/ Red Lists/ Introduction, supra note 13, at 1 (describing the significance of the red lists as they relate to the protection of endangered medicinal plants).

[FN57]. See A. Gigon, Blue Lists: A Conservation Tool Used for Assessing the Enhancement of Threatened Animal and Plant Species, The Swiss Biodiversity Forum (specifying that blue lists are used only in conjunction with the red lists), at http://www.biodiversity.ch/ch/index.html (last visited July 20, 2002).

[FN58]. See Swiss Agency for the Environment, Forests and Landscape, Thematic Report on Benefit-Sharing, 8-9 (2001) (discussing the need to monitor and regulate access to biodiversity and assure fair benefit sharing), at http://www.biodiv.org/world/reports.asp?t=all#S (last visited Aug. 5, 2002).

[FN59]. See id. (outlining that the guidelines provide guidance on the fair sharing of benefits). See

generally Swiss Guidelines, supra note 11 (stating that article 1.1 provides for non-discriminatory access to natural resources; article 7.2 provides that it is necessary for the government to record collected resources and respect the customs and traditions of the local shareholders; and article 8.3 recommends the sharing of intellectual property rights between the local shareholders and the explorers who commercialize natural resources).

[FN60]. See World Summit on Sustainable Development, supra note 1 (remarking that the Johannesburg Summit focused on how countries have implemented Agenda 21 and the CBD).

[FN61]. See TRIPS, supra note 5, art. 27.3(b) (noting that members can exclude from patentability plants and animals, other than microorganisms, and essentially biological processes for the production of plants, other than non-biological and microbiological processes).

[FN62]. See generally J.H. Reichman, The TRIPS Agreement Comes of Age: Conflict or Cooperation with the Developing Countries, 32 Case W. Res. J. Int'l L. 441 (2000) (giving an overview of the TRIPS Agreement, and considering, specifically some of the positive achievements and negative trends in TRIPS since the inception of the TRIPS Agreement).

[FN63]. See TRIPS, supra note 5, art. 65 (providing least-developed countries until 2006, economies in transition and developing countries until 2000, and developed countries until 1996 to comply with the TRIPS Agreement).

[FN64]. See id. art. 27 (stating that patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step, and are capable of industrial application). See generally Richard Wilson, Protection of Traditional Medicine, July 2001, at 8-10 (emphasizing the importance of patents for the preservation of traditional medicinal knowledge and medicinal plants in developing countries), at http://www.cmhealth.org/docs/wg4_paper4.pdf (last visited Aug. 10, 2002).

[FN65]. See TRIPS, supra note 5, art. 27.2 (stating that TRIPS excludes those inventions from patentability to "protect human, animal, or plant life or health, or to avoid serious prejudice to the environment").

[FN66]. See id. art. 27.3(b) (stating that members may exclude plants from patentability).

[FN67]. See Smith, supra note 4, at 152 (discussing that TRIPS allows countries the flexibility to decide whether to protect biological material and process with patents).

[FN68]. See generally TRIPS, supra note 5 (defining the terms for the patentability of plants and biological processing). However, it is unclear what is the rationale. Id.

[FN69]. See id. art. 27.3(b) (stating that the World Trade Organization shall review the provisions of this subparagraph four years after the date of its entry into force). See also World Trade Organization Doha Ministerial Conference, Draft Ministerial Declaration, WT/MIN(01)?DEC/W/1 (Nov. 14, 2001) (reporting that the work in the TRIPS Council on these reviews should look at the relationship between the TRIPS Agreement and the CBD, the protection of traditional knowledge and folklore, and discussing that TRIPS Agreement's development objectives as defined in article 7 should guide the TRIP Council's work), at http://docsonline.wto.org) (last visited Aug. 1, 2002). See generally Matthew Stilwell, Review of Article 27.3(b) Center for Int'l Envtl. Law (June 2001) (analyzing the link between the provisions of article 27.3(b) and development, and the overlapping coverage of TRIPS and the CBD), at http:// www.ciel.org/Publications/pubtae.html (last visited Aug. 10, 2002).

[FN70]. See Symposium on Issues Confronting the World Trade System-Summary Reports by the Moderators, July 6-7, 2001 [hereinafter Issues Confronting the World Trade System] (discussing the issue of divergence or convergence between the CBD and the TRIPS Agreement), at http://www.wto.org/english/forums_e/ngo_ e/ngo_symp2001_repTRIPS2_e.htm (last visited Aug. 4, 2002).

[FN71]. See id. (noting that TRIPS does not discuss traditional knowledge and indigenous people).

[FN72]. See G. Kristin Rosendal, Impacts of Overlapping International Regimes: The Case of Biodiversity, Rev. Multilateralism & Int'l Org., Jan. 1, 2001, at 36 (explaining how TRIPS and the CBD overlap because both introduce opposing regulations aimed at the same issue area), 2001 WL 23902206.

[FN73]. See TRIPS, supra note 5 (setting the general goals of TRIPS).

[FN74]. See id. art. 27.3(b) (noting that article 27.3(b) reads ambiguously).

[FN75]. See Industrial Property Law of Brazil, Law No. 9279, May 14, 1996 (outlining the amended Brazilian patent law in 1996), at http:// www.inpi.gov.br/idiomas/conteudo/law.htm (last visited Aug. 2, 2002).

[FN76]. See TRIPS, supra note 5.

[FN77]. See Robert Sherwood, Intellectual Property in Developing Countries and Judicial Systems, and Economic Development (noting that the 1996 industrial property law in Brazil introduced improvements but was not a great advance, and discussing that the system is suffering from bureaucracy, inadequate judicial system, and weak protection of trade secrets), at http:// www.kreative.net/ipbenefits (last accessed Jan. 31, 2002).

[FN78]. See Industrial Property Law of Brazil, supra note 74, art. 18(II) (stating that living organisms are not patentable).

[FN79]. See id. art. 8 (marking that "anything contrary to morality, decency, public safety, order, and public health is not patentable"). Id. at 18(I).

[FN80]. See id. art. 10 (determining that discoveries of living organisms are not patentable).

[FN81]. See id. art. 10(IX) (stating that all or part of natural living beings and biological materials found in nature, or isolated therefrom, including the genome or germ plasm of any natural living being and the natural biological processes, are not patentable).

[FN82]. See id. (noting that biological processes are not patentable under the patent law of Brazil).

[FN83]. See Arcanjo, supra note 49, at 25 (arguing that patenting of living forms and biological processes in Brazil could guarantee entry of private pharmaceutical companies).

[FN84]. See Switzerland Federal Law on Patents for Inventions, supra note 14 (providing an overview of the minimum requirements to accord a filing date and the requirements for patentability).

[FN85]. See id. art. 2(a) (excluding inventions contrary to public order and morality from patentability).

[FN86]. See id. art. 1(a) (stating that compounds obtained through non-biological and microbiological processes are patentable).

[FN87]. See id. (observing that the language of article 1(a) is ambiguous). See also WTO Council for Trade-Related Aspects of Intellectual Property Rights, Communication from Switzerland, IP/C/W/284 (June 15, 2001) (outlining the view of Switzerland that countries should have the discretion to exclude plants from patentability in their national laws).

[FN88]. Switzerland Federal Law on Patents for Inventions, supra note 14, art. 7(c) (stating that substances or compounds subject of a prior right that have a new use shall be considered new to the extent that they are intended solely for such use). See also id. art. 8(3) (determining that if the invention concerns a process, the effects of the patent shall extend to the immediate products of the

process). See generally A Case for '**Swiss-type' Claims** in Indian Patent Act, The Hindu, Mar. 29, 2001 (reporting that it is necessary to distinguish between a new benefit of a known use of a known molecule and a completely new use), at http:// www.hinduonnet.com/thehindu/2001/03/29/stories/0629000a.htm (last visited Aug. 10, 2002).

[FN89]. See Switzerland Federal Law on Patents for Inventions, supra note 14, art. 7(c) (allowing patents for new uses of known substances).

[FN90]. See Eversheds National BioScience Group, 2nd Pharmaceutical use-The Swiss Type Claim (Dec. 21, 2000) (explaining that the new medical use must be completely new and not simply a modification of an existing treatment or a better method for treating a disease), at http://www.stepc.gr/~katharak/2nd_ Pharmaceutica_use.doc (last visited Aug. 10, 2002).

[FN91]. See id. (stating that research that results in the second medical use is significant and as such is not less worthy of patent protection).

[FN92]. See A Case for '**Swiss-type' Claims** in Indian Patent Act, supra note 88 (arguing that the "Swiss claim" approach is in use in Malaysia, New Zealand, Switzerland, and the United States while India considers introducing it in its patent law because of its significant advantages).

[FN93]. See supra notes 82-90 and accompanying text (outlining the benefits of having patents for secondary use).

[FN94]. See Smith, supra note 4, at 152, 163 (observing that the CBD has "overly broad standards" and that the language of article 27.3(b) is both "sweeping and vague").

[FN95]. See International Chamber of Commerce Commission on Intellectual Industrial Property, TRIPS and the Biodiversity Convention: What Conflict (June 28, 1999) (arguing that there is no conflict between TRIPS and the CBD), at http://www.iccwbo.org/home/menu_intellectual_property.asp (last visited Aug. 10, 2002).

[FN96]. See CBD, supra note 4, art. 16(5) (recognizing that intellectual property rights are important for the implementation of the CBD without directly referring to TRIPS). See also Agenda 21, supra note 3, ch. 16 (failing to incorporate intellectual property protection provisions).

[FN97]. See CBD, supra note 4, art. 16(2) (favoring technology patents, but failing to address patent subject matter). See also Agenda 21, supra note 3, ch. 15 (lacking provisions on patents).

[FN98]. See Issues Confronting the World Trade System, supra note 70 (expressing the opposing views that the two conventions overlap or that they deal with very different issues).

[FN99]. See World Trade Organization Communication from Switzerland, supra note 87 (highlighting that Switzerland favors an adequate protection of biotechnological inventions). See also World Trade Organization, Review of the Provisions of Article 27.3(b): Further View of the United States, IP/C/W/209 (Oct. 3, 2000) (providing the views of the United States that a patent discovery that is isolated and unfound in nature is patentable).

[FN100]. See TRIPS and the Convention on Biodiversity: What Conflict, supra note 95 (asserting that TRIPS takes away rights given to developing countries by the CBD). While the CBD assigns sovereignty rights in the biological resources on the territory of each country, TRIPS allows patents for those resources. See id.

[FN101]. See Kevin McCabe, The January 1999 Review of Article 27 of the TRIPS Agreement: Diverging Views of Developed and Developing Countries Toward the Patentability of Biotechnology, 6 J. Intell. Prop. L. 41, 56 (1998) (stating that TRIPS affects developed and developing countries differently).

[FN102]. See id. (outlining the views of developed and developing countries with regards to the

revision of TRIPS article 27.3(b)). See also Christopher Mayer, The Brazilian Pharmaceutical Industry Goes Walking From Ipanema to Prosperity: Will the New Intellectual Property Law Spur Domestic Investment?, 12 Temp. Int'l & Comp. L.J. 377, 396 (1998) (noting that if patent protection had been in place for medicines, then sales by U.S. pharmaceutical companies in Brazil would have increased by almost fifty percent).

[FN103]. See C.F. [Constitution] art. 225 (Braz.)(1988) (amended in 1993) (dedicating one entire chapter to environmental protection), at http:// www.uniwuerzburg.de/law/br00000_.html (last visited on Aug. 10, 2002). See also Bv. Cst. Cost. Fed. [Constitution] arts. 73, 74, 77, 78, 120 (Switz.) (1999) (modified in 2001), at http://www.swissemb.org/legal/const.pdf (last visited July 21, 2002) (addressing issues such as protection of the environment, forests, nature and cultural heritage, and gene technology in the non-human field).

[FN104]. See C.F. art. 225 (Braz.) (stating that all persons have right to an ecologically balanced environment). See also Bv. Cst. Cost. Fed. art. 73 (Switz.) (noting that the Confederation and the Cantons shall strive to establish a durable equilibrium between nature, in particular its capacity to renew itself).

[FN105]. See C.F. art. 225 (Braz.) (declaring that the government and the people of Brazil must preserve and country's rich biodiversity). See also Bv. Cst. Cost. Fed. art. 74 (Switz.) (articulating that the Confederation has the duty to legislate on the protection of Swiss people and their natural environment against harm and nuisance).

[FN106]. See C.F. art. 225(1)(II) (Braz.) (stating that the government of Brazil must preserve the country's rich natural resources and must supervise entities engaged in research and handling of genetic material). See also Bv. Cst. Cost. Fed. art. 120 (Switz.) (providing that the Swiss Confederation shall legislate on the use of genetic material of animals, plants, and other organisms, and establishing that in doing so it shall consider the dignity and security of men, animals and the environment).

[FN107]. See Bv. Cst. Cost. Fed. arts. 77, 78(4) (Switz.) (stating that the government and the people of Switzerland shall protect forests and endangered species from extinction). See also C.F art. 225(1)(VII) (Braz.) (providing for the protection of flora).

[FN108]. See Bv. Cst. Cost. Fed. art. 78 (Switz.) (stating that the Confederation shall preserve natural, cultural, and historical monuments and should take into account public interest). See also C.F. arts. 225(1)(II)& (VII)(4) (Braz.) (preserving the integrity of the country's natural resources and enlisting the territories that are part of the national patrimony).

[FN109]. See supra notes 98-100 and accompanying text (discussing how the constitutions of Brazil and Switzerland demonstrate both countries' concern about the protection of the environment).

[FN110]. See generally supra notes 101-107 and accompanying text (analyzing the constitutional biodiversity legal protection in Brazil and Switzerland).

[FN111]. See id. See infra notes 112-23 and accompanying text (comparing richness of pharmaceutical biodiversity in Brazil and Switzerland).

[FN112]. See Swiss Agency for the Environment, Forests and Landscape, Clearing House Mechanism Biodiversity Switzerland at a Glance/Geography/Alps-The Swiss Alps (mentioning that forests in the Alps include mainly conifer trees above 1,000 meters), at http://www.buwal.ch/nachh/chm/e/ch/geo/geo_ alps.htm (last visited Aug. 7, 2002).

[FN113]. A Summer Holiday in the Alps, Deutsche Presse-Agentur [Munich], June 11, 2002 (highlighting that the Alps are a special region of culture and nature), LEXIS, News Group File.

[FN114]. See Bernhard Schmidt, State and Development of Biodiversity in Switzerland, Institut für Umweltwissenshaften (stating that Switzerland is one of the European countries with the highest

biodiversity), at http:// www.biodiversity.ch.ch.index.html (last visited Aug. 5, 2002).

[FN115]. See id. (observing that Swiss people recognize the unique natural heritage of the Alps since an early age).

[FN116]. See id. (asserting that Switzerland is perhaps the only country in the world with a high population density, large economic activities, and rich biodiversity).

[FN117]. See Sturm, supra note 27 (discussing the rich biodiversity in the Brazilian rainforest). See also Charles Clover, Drugs Companies Are Told To Pay for Plant 'Plundering,' The Daily Telegraph (London), Apr. 18, 2002 (reporting that trade in medicinal plant products is worth 23 billion British pounds per year, and asserting that drugs and perfumes companies plunder plants in developing countries without paying compensation to the countries where those natural resources originate), LEXIS, News Group File.

[FN118]. See Amazonia in Numbers (providing biodiversity data about the Brazilian Amazon rainforest), at http://www.bioamazonia.org.br/numerose.htm (last visited Aug. 1, 2002). See also First National Report of Brazil, supra note 8, at 12-13 (estimating the value of biodiversity in Brazil to be much higher than the country's GDP).

[FN119]. See Amazonia in Numbers, supra note 118 (noting that the Brazilian Amazon forest contains somewhere around one-forth of the world's plants).

[FN120]. See Corazza, supra note 9, at 1 (discussing the plague of biodiversity in the Brazilian rainforest). The Brazilian Amazon forest has thirty percent of all the superior plants in the world. See id. International companies exploit the natural resources of the Brazilian Amazon forest for profitable purposes. See id.

[FN121]. See Reuters News Service, Axel Bugge, Brazil Amazon Destruction Down But Still Alarming, Planet Ark, June 13, 2002 (mentioning that the rate of forest destruction in the Brazilian rainforest worries environmentalists), at http://www.planetark.org/dailynewsstory.cfm/newsid/16404/story.htm (last visited Aug. 5, 2002). See also Janelle Kellman, The Brazilian Legal Tradition and Environmental Protection: Friend or Foe, 25 Hastings Int'l & Comp. L. Rev. 145, 148 (2002) (discussing that agricultural uses and road building are among the main factors behind the depletion of the Amazon forest).

[FN122]. See Bugge, supra note 121 (providing information about the rate of destruction of the Amazon rainforest in Brazil from the National Institute for Space Research).

[FN123]. See id. (highlighting that the government has a vital role to play in the protection of the natural environment in Brazil). In 2000, fires in the rainforest decreased due to increased government monitoring. See id.

[FN124]. See Corazza, supra note 9, at 3 (noting that a North-American company has catalogued over 7000 Amazon plants without paying anything for their gathering).

[FN125]. See David Tilford, Saving the Blueprints: The International Legal Regime for Plant Resources, 30 Case W. Res. J. Int'l L. 373, 428 (1998) (arguing that the CBD recognizes the right of developing countries to demand compensation for their natural resources).

[FN126]. See Naomi Roht-Arriaza, Of Seeds and Shamans: The Appropriation of the Scientific and Technical Knowledge of Indigenous and Local Communities, 17 Mich. J. Int'l L. 919, 928 (1996) (stating that consulting indigenous people could be very important for the discovery of new plant-derived drugs). See also JoAnn Kawell, Report on Science and Technology, NACLA Report on the Americas, Mar. 1, 2002, at 1-2 (stating that local experts are the best source of knowledge about which plants should be screened), 2002 WL 12669949.

[FN127]. See Kimberly Johnson, The Benefits of Studying Medicinal Plants and Ethnobotany,

Biodiversity and Human Health (discussing that the use of medicinal plants has a long history and people continue to use plants as a source of medicinal cure today), at http:// www.wms.org/biod/value/medplants/med_plants2.html (last visited Aug. 10, 2002).

[FN128]. See id. (noting that medicinal plants have had a wide use in Europe and that the writings of Theophrastus Bombastus von Hohenheim remain a landmark).

[FN129]. See Lucy Hoareau and Edgar DaSilva, Medicinal Plants: A Re-Emerging Health Aid, Electronic Journal of Biotechnology, Aug. 15, 1999, vol. 2, No. 2 (explaining that interest in medicinal plants has re-emerged as a result of the rising costs of prescription drugs and bioprospecting of new plant-derived drugs), at http://www.ejb.org/content/vol2/issue2/full/2/ (last visited Aug. 10, 2002).

[FN130]. See id. at 4 (mentioning that the adonis vernalis is specific to Switzerland, Sweden, and Germany).

[FN131]. See Thyme, Healthnotes Online (describing the traditional medical uses of thyme to treat bronchitis and gingivitis), at http:// 63.65.255.14/Thyme.htm (last visited July 31, 2002).

[FN132]. See Horehound, Healthnotes Online (reporting that horehound is a cough suppressant and a bitter digestive tonic), at http:// 63.65.255.4/Horehound.htm (last visited July 31, 2002).

[FN133]. See Alesandra Dalevi, Green Piracy, Brazil (noting that in Brazil there is a boom of natural medicine and that Brazil ranks second in the world after India in the use of natural medicine for treatment), at http:// www.brazil-brasil.com/cvrjul97.htm (last visited on June 14, 2002).

[FN134]. See id., at 9 (noting that in Brazil two thousand pharmacists produce 3,000 medicinal formulas using minerals, animals, and plants).

[FN135]. See Antonio Guedes & Maria Sampaio, Genetic Resources and Traditional Knowledge in Brazil, Brazilian Agric. Res. Corp. Oct. 30- Nov. 1, 2000 (stating that about 400,000 native Indians live in Brazil today in 215 ethnic groups and that they speak 180 different languages), at http:// r0.unctad.org/trade_env/test1/openF1.htm (last visited Mar. 14, 2003).

[FN136]. See Corazza, supra note 9, at 4 (mentioning that the Body Shop uses oil of Brazilian nuts for its creams and shampoos).

[FN137]. See id. (noting that Aveda produces cosmetics from the plant urucum).

[FN138]. See id. (stating that pau-rosa is on the list of endangered species).

[FN139]. Alessandra Dalevi, supra note 133, at 7 (reporting that shamans already researched about 7000 plants before indigenous people brought to their attention important medicinal plants). Shamans could make significant contributions to the pharmaceutical industry. Id.

[FN140]. See Conserving Indigenous Knowledge- Integrating New Systems of Integration, UNDP, CSOPP, at 2 (comparing plant biodiversity among countries and placing Brazil on the top of the chart with 55,000 species of plants), at http://www.undp.org/csopp/CSO/NewFiles/docknowledge2.html (last visited Aug. 5, 2002).

[FN141]. See supra notes 140-44 (discussing medicinal uses of Brazil's tropical plants).

[FN142]. See Dalevi, supra note 133, at 1 (asserting that costs of researching medicinal plant uses are much less than the costs associated with the production of new synthetic drugs). Salegen is a medicine produced in the United States from medicinal plants found in Brazil. Id.

[FN143]. See id at 2 (stating that American foreign companies that conduct bioprospecting in Brazil could have saved much valuable research time if they knew the meanings behind the Indian names of the herbs).

[FN144]. See id at 2 (believing that foreign pharmaceutical companies unfairly exploit Brazil, according to Darrell Posey, Director of the Program for Traditional Resource Rights at the Oxford Center for the Environment in the United Kingdom and Researcher for the Brazilian National Council for Science and Technology).

[FN145]. See id. (stating that $5.4 billion do not go to indigenous people around the world to compensate them for their traditional knowledge).

[FN146]. See id. (noting that Brazil receives 0.001 percent from the commercial utilization of its medicinal plants).

[FN147]. See Dalevi, supra note 133, at 3 (Professor Laymert Garcia from the University of the Campinas in Sao Paulo saying that bioprospectors take advantage of the lack of permanent legislation to regulate commercialization of biodiversity).

[FN148]. See Brown, supra note 39 (explaining that Brazil is the world leader in some types of cancer research, but dialogue among industry, the scientific community, and the government is difficult).

[FN149]. See id. (asserting that Brazil's research science is on the cutting edge and "the potential for human medicine is huge"). However, the lack of partnership between the private and public sector in Brazil has damaging consequences for the commercialization of Brazil's rich medical plant resources. See id.

[FN150]. See id. (highlighting that if clear rules continue to be lacking, business opportunities will decrease).

[FN151]. See Guedes & Sampaio, supra note 135, at 3 (stating the necessity of guidance on how to implement the provisionary law and that the National Research Council, the government agency that previously authorized international scientists to collect genetic resources, awaits a clarification of the rules).

[FN152]. See Brown, supra note 39 (assessing that the outcome of the Novartis deal has negative consequences for the future development of the biotechnology sector in Brazil). As a result, there are many designed projects, but little investment. See id. For instance, FIR Capital Partners, a small biotechnology company in Brazil, has a $75 million investment fund and plans to spend one-third of it for biotechnology projects. See id. However, the firm is reluctant because the government of Brazil lacks consistency in its actions and permanent biodiversity laws do not exist in Brazil. See id.

[FN153]. See id. (estimating that other companies will also remain reluctant to sign contracts in Brazil, because the Brazilian government fails to enforce contracts).

[FN154]. See Brown, supra note 39 (detailing that a board member of BioAmazonia denounced the contract and the government of Brazil cancelled the deal under the growing pressure from environmental groups).

[FN155]. See id. (quoting the CEO of Novartis Pharma that Novartis "would not contribute a nickel" toward the Biotechnology Center in the Amazon). See also Larry Rohter, Brazil Moves to Protect Jungle Plants from Foreign Biopiracy, N.Y. Times, Dec. 23, 2001, A1, at 4, col. 3 (reporting that many pharmaceutical companies and laboratories hesitate to sign bioprospecting agreements in Brazil after the Novartis contract failed apart), LEXIS, News Group File.

[FN156]. See supra notes 138-53 and accompanying text (demonstrating that foreign companies express no interest in signing cooperation agreements with the Brazilian government because laws in Brazil constantly change and it is difficult to overcome the mutual distrust between foreign researchers and the Brazilian government).

[FN157]. See Geoff Dyer, Brazilians Hope to Turn Plants into Profits: Biotechnology Can Make Money

from the Rainforest, but Will Any of the Profits Stay in the Country?, Fin. Times (London), Aug. 28, 2001, at 8 (assessing that the value of Brazil's biodiversity is about $2 trillion, nearly four times Brazil's annual GDP), LEXIS, News Group File.

[FN158]. See Andrew Revkin, Biologists Sought a Treaty; Now They Fought It, N.Y. Times, May 7, 2002, at F1 (observing that the CBD seriously impedes biologists' efforts to explore new biological resources), LEXIS, News Group File.

[FN159]. See id. (giving an example how criminal penalties might be severe, and explaining that the Federal Police of Brazil arrested an American scientist who studied the Amazon forest and seized his collection even though he had all the necessary visas).

[FN160]. See id. (mentioning that a German botanist pursuing a science doctorate degree at Yale University studied plants in the Brazilian Amazon when regional newspapers announced that she was collecting genetic material in order to develop new drugs). The resulting difficulties forced her to abandon her research. See id.

[FN161]. See Dalevi, supra note 133, at 11 (mentioning that the military of Brazil keeps foreigners out of the Amazon). See also Mark Stevenson, China, Brazil, India, 9 Other Nations Form Alliance Against Biopiracy, Associated Press, Feb. 18, 2002 (reporting that the new alliance against biopiracy would like to see more equal trade rules on patenting and a fairer benefit-sharing mechanism), LEXIS, News Group File.

[FN162]. See Dalevi, supra note 133, at 11 (stating that the nationalist movement believe that the entry of foreign scientists in the Amazon forests is against the country's national security and indicating that their motto is "Fight for the Forest").

[FN163]. See Biopiracy in Brazil (noting that Selva Viva, an NGO created by a Swiss citizen, was brought to court by the local Roman Catholic Church in Brazil for illegally stealing indigenous knowledge, and discussing that this criminal case resulted from a law implemented in the state of Acre, which protects biodiversity and imposes harsh penalties against foreigners who claim rights in the Amazon forest), at http://www.dmac.co.uk/gen/a-sbio.html (last visited Aug. 9, 2002).

[FN164]. See supra notes 156-61 and accompanying text (analyzing how harsh visa restrictions, nationalistic tension, and severe criminal penalties in Brazil hinder innovation).

[FN165]. See First National Report of Brazil, supra note 8, at 160 (discussing the latest changes in the Brazilian intellectual property legislation).

[FN166]. See Key Facts, supra note 9 (providing statistics about Brazil's investment in scientific research and development).

[FN167]. See Gerald Mossinghoff & Ralph Oman, The World Intellectual Property Organization: A United Nations Success Story, 160 World Aff. 104, 105 (1997) (discussing the successes achieved by the World Intellectual Property Organization in Geneva). See also Alan Holmer, Patent Protection is Key, USA Today, Oct. 29, 2001 (emphasizing that strong patents give research-based companies the incentives to invest the average $500 million needed to discover and develop each new drug), at http://www.usatoday.com/news/comment/2001-10-29- ncoppf.htm (last visited Aug. 10, 2002). See generally John Baremore, Don't Shoot the Messenger: Congress and the Prospect of Patent Harmonization, 44 Loy. L. Rev. 761 (1999) (stating that a nation's patent law is its cornerstone for economic development).

[FN168]. See Verma, supra note 2, at 4 (highlighting that intellectual property rights protection is crucial for investment decisions of businesses).

[FN169]. See Stevenson, supra note 15, at 1152 (emphasizing that trade secrets could be used as an intellectual property tool to protect traditional medicinal knowledge).

[FN170]. See Edwin Mansfield, Intellectual Property Protection, Foreign Direct Investment, and Technology Transfer, at 21 (presenting empirical evidence between the respect and disrespect for patents by the developing countries and foreign direct investment flow by developed countries to those developing countries), at http://www.ifc.org/economics/pubs/discuss.htm (last visited Aug. 11, 2002).

[FN171]. See id. (concluding that strong patent protection fosters larger foreign direct investment). See also Keith Maskus, Intellectual Property Rights and Economic Development, 32 Case W. Res. J. Int'l L. 471, 494 (2000) (discussing that intellectual property protection is very important for development; however, the cost of administration and enforcement of intellectual property rights could be burdensome as developing countries implement stronger intellectual property systems).

[FN172]. See John Thomas, An Examination of the Issues Surrounding Biotechnology Patenting and Its Effect Upon Entrepreneurial Companies, CRS Report for Congress, Aug. 31, 2000, at 7 (noting that the biotechnology industry is known for the heavy expenditures on research and development and a reliance on patent protection).

[FN173]. See Viana, supra note 8 (stating that data from the National Institute of Industrial Property in Brazil demonstrates that in 1999, after the 1996 Patent Law came into effect, the number of patents granted in the biotechnology pharmaceutical industry has risen on average twenty percent a year).

[FN174]. See World Health Organization, World Health Organization Medicine Strategy 2002-2005 (2002) (discussing the widespread use of traditional medicine and ethnobiological knowledge, the international legal framework for access to traditional medicine, as well as the international and national resources for traditional medicine), at http://www.who.int/medicines/library/trm/trm_strat_eng.pdf (last visited Aug. 11, 2002).

[FN175]. See Revkin, supra note 158, at F1 (adding that in 2000, Brazil stopped exports of biological samples from the Amazon forest even to Brazilians working abroad).

[FN176]. See id., at F1 (reporting that a researcher from Singapore abandoned a project in the Brazilian Amazon and moved his research to a different country, where he received better treatment).

[FN177]. See Swiss Guidelines, supra note 11, art. 3(1) (favoring a fair and equitable sharing of genetic resources).

[FN178]. See id. art. 11(2) (noting that the government should issue access permits within a reasonable time and should facilitate access to genetic resources).

[FN179]. See id. arts. 6, 7, 8 (including guidelines about responsibilities of users and providers during and after the research process).

[FN180]. See id. See infra notes 181-83 and accompanying text (recommending that the provisions from the Swiss guidelines could be pertinent to Brazil).

[FN181]. See Swiss Guidelines, supra note 11, art. 1(1) (denoting that access to natural resources should be non-discriminatory).

[FN182]. See id. art. 7(4) (noting that the Swiss guidelines do not require that foreign companies perform their research in Switzerland).

[FN183]. See id. arts. 10, 11, 12 (noting that donors should cooperate with other stakeholders to foster collaboration in the collection of genetic resources).

[FN184]. See id. arts. 8(2), 8(3) (highlighting that sharing of intellectual property assets is not a requirement).

[FN185]. See id. art. 15(1) (encouraging the use of a mediator during the negotiation of mutually agreeable contract terms).

[FN186]. See id. See infra notes 187-88 and accompanying text (outlining how ecotourism should become part of the draft law in Brazil).

[FN187]. See First National Report of Brazil, supra note 8, at 181 (discussing the use of ecotourism in Brazil).

[FN188]. See Laurie Goering, Brazil Wants Cut of Biotech Firms' Jungle Plunder, Trib. Company, July 6, 1999 (stating that tourists take away plants and act as biopirates in the Amazon), at http:// forests.org/archive/brazil/biotechs.htm (last visited Aug. 5, 2002).

[FN189]. See supra notes 186-88 and accompanying text (implying the importance of ecotourism for the protection of the environment).

[FN190]. See Mae-Wan Ho, Brazilian Shamans Denounce Biopiracy, ISIS News, no. 13/14, Feb. 2002 (discussing the increasing concern among indigenous people in Brazil about biopiracy), at http://www.i-sis.org.uk/isisnews/I-sisnews13- 16.php (last visited Aug. 10, 2002). See also Corazza, supra note 9 (reporting that biopirates arrive on tourist visas and that it is not easy to catch them).

[FN191]. See National Report of Switzerland, supra note 52, at 39-42 (mentioning that tourism in Switzerland ranks third in exports and one person out of eleven works in the field of tourism).

[FN192]. See "Code of Conduct" to Rein in Tourists, Save the Earth, Deutsche Presse-Agentur, May 22, 2002 (stating that Switzerland, Austria, and Germany are the three countries "world champions of travel"), LEXIS, News Group File.

[FN193]. See National Report of Switzerland, supra note 52, at 39 (discussing the government objectives to adapt regional tourism to the ecological and landscape problems).

[FN194]. See "Code of Conduct" to Rein in Tourists, Save the Earth, supra note 192 (stating that principles of ecotourism apply equally in rich and poor countries). Tourism guidelines are necessary since the number of tourists in Europe and Latin America is expected to double over the next decade. Id.

[FN195]. See Valerie Boisvert & Armelle Caron, The Convention on Biodiversity: An Institutionalist Perspective of the Debates, 39 J. Econ. Issues 1, Mar. 1, 2002, at 11 (arguing that the current restrictions on access to biological material in Brazil have their limits and stating that those measures would further increase the problems), 2002 WL 17669311.

[FN196]. See supra notes 80-89 (explaining how the "Swiss claim" approach works in Switzerland and its advantages). See generally Teresa Scasa, Patents for Second Medical Indications and Their Potential Impact on Pharmacare in Canada, 9 Health L.J. 23 (2001) (discussing that "**Swiss type" claims** have been adopted in Switzerland, the United States, the United Kingdom, Sweden, and Germany).

[FN197]. See A Case for "**Swiss-type" Claims** in Indian Patent Act, supra note 88 (discussing how the "Swiss claim" patents work).

[FN198]. See id. (discussing the significance of "Swiss claim" patents).

[FN199]. See Rolf Auf der Maur, Introduction to Swiss Intellectual Property Law 22, (vol. 3 (1995)) (providing a brief overview of Swiss copyright, patent, trademark, conflicts of law, and civil procedure laws), available at http:// www.baerkarrer.ch/4publications/4_3_3cont.html (last visited Aug. 11, 2002).

[FN200]. See supra notes 195-199 (implying the significance of "Swiss claim" patents to protect

environmental resources). See also Jane Calvert & Greg Lynch, The Swiss-Style Claim Saga- Is this the End?, Patent Prose, Jan./ Feb. 2000 (mentioning that "Swiss type" patents are favorable to scientists and companies involved in research to find new medical uses for compounds already known to have pharmaceutical properties), at http:// www.bsw.com/articles22.html (last visited Aug. 10, 2002).

[FN201]. See Patents for Methods of Medical Treatment of Humans (emphasizing that a "Swiss claim" enables second medical uses to obtain patent protection), at http://www.med.govt.nz/busit/int_prop/patentsreview/patentsreview-09.html #P556_133581 (last visited Aug. 10, 2002).

[FN202]. See id. (asserting that in the absence of "Swiss claim" patents, discoverers of second medical have no incentive to invest in second medical uses, because cost of research is high and benefits are low).

[FN203]. See Swiss Clearing House Mechanism Biodiversity/ Red Lists/ Introduction, supra note 13 (discussing that Switzerland has introduced the red lists for endangered species and is presently implementing a red book on tourism).

[FN204]. See id. (explaining that red lists provide information about endangered species).

[FN205]. See Gigon, supra note 57 (analyzing the significance of the blue lists to increase efforts to protect the environment).

[FN206]. See id. (describing the positive effect of the concurrent use of red and blue lists in Switzerland).

[FN207]. See Brazil Sees Promise in Jungle Plants, But Tribes See Peril, supra note 39 (noting that Brazil recently created a centralized bank to store traditional knowledge and explaining that to use that information a researcher must pay fees).

[FN208]. See Industrial Property Law of Brazil, supra note 75, art. 11(1) (stating that an invention is not new if it comprises everything made available to the public, by means of written or oral description, or in any other way before the filing date of the patent application).

[FN209]. See Caroline Ryan, Patent to Protect Ancient Knowledge, BBC News, Feb. 19, 2002 (stating that the Indian government created a Traditional Knowledge Digital Library to record traditional treatments and prevent them from being patented as novel ideas, and that this new creation could be a model for countries in Latin America), at http://news.bbc.co.uk (last visited Feb. 19, 2002).

[FN210]. See Brazil to Map Potential Medicinal Plants, Reuters, Feb. 25, 2002 (stating that IBAMA has created the database of medicinal plants to prevent commercial use of the plants outside Brazil), at http:// www.ictsd.org/biores/02-03-07/inbrief.htm (last visited June 12, 2002).

[FN211]. See supra notes 180-83 (implying that red list classification could work well in Brazil).

[FN212]. See supra notes 182-83 (highlighting that blue lists in Brazil could encourage decision-makers and the public to improve further their nature conservation efforts).

[FN213]. See id. (deducing that the positive effects of red lists in Switzerland could apply in Brazil).

[FN214]. See supra notes 129-60 (analyzing why Brazil presently does not yield benefits from the commercialization of its medicinal plant resources).

[FN215]. See supra notes 161-77 and accompanying text (recommending that Brazil make its medicinal plants more accessible to scientists).

[FN216]. See supra notes 189-93 and accompanying text (recommending that Switzerland adopt the

"Swiss claim" patents).

[FN217]. See supra notes 171-76 and accompanying text (encouraging Brazil to incorporate ecotourism clauses in its draft law).

[FN218]. See supra notes 180-90 and accompanying text (suggesting that "red lists" could be vital for protection of pharmaceutical biodiversity in Brazil).

[FN219]. See supra notes 95-128 and accompanying text (establishing the basis for comparison between Brazil and Switzerland and why the Swiss model could be adaptable in Brazil).

[FN220]. See Michael Huft, Indigenous Peoples and Drug Discovery Research: A Question of Intellectual Property Rights, 89 Nw. U.L. Rev. 1678, 1690-91 (1995) (stating that during the last decade medicinal plants have become an important source for plant-derived drugs to treat various forms of cancer).

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*381 PATENTABILITY OF METHODS OF MEDICAL TREATMENT: A COMPARATIVE STUDY

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I. INTRODUCTION

The patentability of methods of medical treatment is a developing issue worldwide. The issue eludes an easy solution due in part to its dual roots in patent law and medical law. The issue is further complicated by numerous ethical considerations surrounding the patenting of methods of medical treatment.

An analysis of the pertinent issues involved brings together two very different areas of law: patent law and medical law. [FN1] Patent law generally concerns property, its protection and the revelation of new technology. A basic tenet of patent law is ownership and the ability to exclude as a reward for revealing an inventor's new technology. [FN2] A fundamental trait of patent law is its reliance on economic motivation and reward as a means to encourage innovation, development and dissemination of technology. It is this trait which distinguishes patent law from medical law the most. Medical law, by contrast, has its origins in the Hippocratic Oath. A primary goal of medicine is not the innovation and development of technology, but the preservation of human life. In pursuit of this goal, physicians have routinely shared new advances in the art of medicine. [FN3] Furthermore, medical law is not confined to a statute, but is governed largely by ethics. [FN4]

It is the object of this article to categorize and define generally the various methods of medical treatment, and to provide a glimpse into the *382 legal environment regarding patentability of methods of medical treatment in selected areas of the world.

II. CATEGORIES OF MEDICAL TREATMENT

Methods of medical treatment can be divided into three main categories: methods of therapeutic treatment, methods of elective treatment and diagnostic methods. Therapeutic and elective methods may be further divided into those that are surgical and non-surgical. An appropriate definition for therapeutic treatment may be borrowed from European case law, where extensive review has produced consistent terminology. [FN5] Accordingly, "therapeutic treatment" may be defined as a course of care undertaken with the "intention to improve the health of the human or animal [FN6] being treated." [FN7] More specifically, "therapy" may be defined as covering "any treatment which is designed to cure, alleviate, remove or lessen the symptoms of, or prevent or reduce the possibility of contracting any disorder or malfunction of the human or animal body." [FN8] A general guideline for identifying therapeutic methods is that where a medical method must be performed by a physician or under the guidance of a physician [FN9] and is related to improving the health of the human or animal being treated, that method may be taken to be therapeutic. It is clear from the above definitions of "therapeutic" that surgical methods form a subset. "Surgery" has been defined to mean "... the field of medicine involving the healing of diseases or accident injuries, or remedies against physical defects by means of a surgical intervention performed on a ... body." [FN10] Elective treatment may be defined as treatment of a body in a manner distinctly non-therapeutic in nature, or treatment not directly relating to improving the health of the human or animal being treated. [FN11] Diagnostic methods generally include those methods "... in which the examination, i.e., both the determination of the present state of health *383 and the symptoms of illness, is carried out directly on ... [a] body," [FN12] or in a purely medical sense, the "... recognition, differentiation and localization of pathological conditions." [FN13] These categories and definitions will become important when analyzing the patentability of methods of medical treatment in selected areas around the world.

III. ISSUES AND CONSIDERATIONS AFFECTING THE PATENTABILITY OF METHODS OF MEDICAL TREATMENT

Theoretically, the art of medicine is not motivated by economics. However, that is rapidly changing. For example, in the U.S., the onslaught of managed healthcare in recent years, while promoting efficiency and reduced medical costs, has also caused a decline in physician salaries and independent

medical judgement. [FN14] Many of the ethical arguments lodged against patenting methods of medical treatment are becoming less important with the new wave of managed health care, especially in the U.S. Yet there still are valid issues remaining which have shaped and continue to shape the policies of nations worldwide in the overlapping areas of patent law and medical law. Many of these issues tend to confine themselves to surgical methods since these methods do not generally involve the use of a product and therefore represent an inventive idea in its most abstract form.

One issue surrounding the patentability of methods of medical treatment concerns the innovation of medical technology. A practical benefit conferred by patent law is the encouragement of investment in research and development. [FN15] By conferring upon a developer of an invention a fixed period to exploit it, the developer is thus able to recoup the initial expenditure used for the invention's development.

Many have suggested, however, that the promise of patent protection is unnecessary to attract research capital in the medical field. Indeed, the American Medical Association has stated this position thusly:

[w]hile the argument that the patenting of medical processes is necessary to enable and promote procedural advances seems strong initially, there is no evidence of the argument's empirical soundness. Medical process patents have been possible [in the U.S.] since the early 1950's but were rarely issued until recently. The fact that medicine advanced rapidly from World War II to the late 1970s despite the absence of medical process patents undermines the central claim that economic incentive is ***384** needed to induce innovation in the realm of medical procedures. In addition, although patents can provide economic benefits to inventors, the medical field has, over the years, established its own internal system of rewards including recognition and respect for discoveries through the publication of findings in respected medical journals and other media. [FN16]

Similar views are echoed by an Australian commentator, who writes:

[t]he economic argument is indeed a strong one in its terms, but it suffers from one vital defect, namely, the absence of empirical data to support it. It is simply no more than the barest of hypothesis. There is, of course, also little or no empirical data to support the proposition that research into and investment in new methods of medical treatment would proceed in the same manner and to the same degree without a patents incentive as they would with one. [FN17]

The views expressed by these commentators downplay the fact that often "the evil sought to be avoided--a monopoly on a healing art--is a necessary pre-condition for the good sought--the specific advance in medical science." [FN18] An example may be drawn from the Surrogate Embryo Transfer (SET) technology of the 1980s. SET involves a procedure whereby an embryo from a donor women's womb is transferred to the womb of an intended recipient. [FN19] The technology was financed by U.S.$500,000 in investment funds after the National Institute of Health declined to fund the project. [FN20] In the absence of patent protection, it is unlikely that SET technology would have developed. [FN21] Concededly, medical research and innovation would still continue without the assistance of patent protection, but as the current trend favors managed health care, competitiveness and economic advantage become increasingly important.

A second important consideration with regard to the patentability of methods of medical treatment is the dissemination of information. Traditionally, the medical community has promoted the free flow of information ***385** through the publication of findings in journals. [FN22] Opponents of method of medical treatment patents argue that this form of information transfer is more quickly disseminated than if the patent system were to be used. [FN23] In many countries, a patent application's content will not be published until 18 months after the priority date. [FN24] However, in many other countries, inventors may publish their work immediately after the filing date and still obtain a patent. [FN25]

In order to obtain a patent in many areas around the globe, there is usually a requirement of enablement. [FN26] To meet the enablement requirement, typically the invention must be adequately described such that a person skilled in the art or profession would understand it. The lack of an enablement requirement in medical journals may lead to inadequate disclosure and less dissemination of information. [FN27] Additionally, not all inventions get published in medical journals. [FN28] Publication in medical journals arguably is the quickest and most efficient method of disseminating information, but inadequate disclosure may result. Additionally, as managed health care assumes a larger role in the profession, many physicians or organizations may choose, in the absence of patent protection, to protect their investment in a new procedure by practicing it in secret in order to prevent wide-spread use and to maintain a competitive advantage. [FN29] This will force many to seek trade secret protection as the only means of protecting their propriety interests in technology. [FN30] The

use of trade secret protection frustrates the goals of both patent law and the medical profession in that dissemination of new medical technology is arrested.
A third issue arises concerning the accessibility of patented methods to physicians. A general concern is that patenting methods of medical treatment may lead to unavailability of a method due to a patentee's ***386*** unwillingness to license it. This may lead to situations in which a patient will not receive the best medical care available. This view is best illustrated by the comments of Sheppard, J., of Australia:
[i]t is not going too far, I think, to say that the Court should not contemplate the grant of letters patent which would give to one medical practitioner, or perhaps a group of medical practitioners, a monopoly over, for example, a surgical procedure which might be greatly beneficial to mankind. Its denial might mean the death or unnecessary suffering of countless people. I cannot think that this is really what the medical profession as a whole would seek to achieve. Its whole history is a denial of this proposition. [FN31]
Although it is possible that insufficient access may result from a patentee's unwillingness to grant licenses, it is unlikely to occur. [FN32] In an industrial setting, a manufacturer can be a sole licensee and do quite well. On the other hand, a medical practitioner patentee would find it unprofitable not to grant licenses if money is a concern. As a matter of economics, a medical practitioner who holds a patent on a medical method may find it difficult to treat a large number of people over an expansive area. If the practitioner were to license the method, the practitioner could maximize his or her income. In this situation, medical ethics and economics would favor a patentee granting multiple licenses. Alternatively, if the practitioner is located in a small country, he or she may be less likely to grant licenses and accessibility may become a problem.
A fourth issue in need of attention is the possible conflict of interest that could occur if a physician is a licensee of a particular method of treatment. As suggested by some commentators, it would be in the physician's financial interest to recommend the licensed method over others that may be as effective, but less expensive. [FN33] Alternatively, if the physician is not a licensee, the temptation may arise to avoid supplying a patient with the better method in order to avoid licensing fees. [FN34]
Proponents of medical treatment method patents point out that physicians have a duty to tell the patient all the alternatives when discussing a course of treatment, as well as a fiduciary and ethical duty to act in the ***387*** patient's best interest. [FN35] A failure to abide by these duties incurs the risk of a medical malpractice suit, at least in the U.S. [FN36]
A fifth issue involves a patient's expectation of privacy in his or her relationship with physicians. In an infringement suit, a patentee may need access to medical records, which could compromise the patient's privacy. [FN37] However, in this situation withholding the patient's name would protect the patient's privacy interests. [FN38]
A sixth issue of concern is cost. Opponents of medical treatment method patents argue that granting monopoly status to medical methods of treatment will allow patentees to charge monopoly prices, contributing to the already high cost of health care. [FN39] In addition, patent prosecution costs and enforcement costs must be dealt with. Other commentators have noted that managed health care greatly reduces monitoring costs [FN40] and that typically, the patented procedure is cheaper than the unpatented alternative. [FN41]
A seventh issue is physician autonomy. Concern has been expressed that fear of infringement and resulting lawsuits may affect physician decisions. Some physicians may not employ new techniques until uncertainty over infringement is resolved. [FN42] Some medical method patent opponents feel that physicians should not have to worry about a lawsuit every time they employ a new method. [FN43] There is little disagreement that medical method patents would add another restraint to the practice of medicine. However, physicians have already dealt effectively with restraints on their practice, most notably managed health care, insurance compensation and (at least in the U.S.) medical malpractice actions.
An eighth issue involves a perceived ethical conflict with the Hippocratic Oath. One commentator has stated that "[g]ranting medical process patents gives every appearance of supporting private gain at the expense of the public good." [FN44] Traditionally, the public good has been served by open sharing of information among physicians [FN45] and adherence ***388*** to the Hippocratic Oath. [FN46] Social and economic events of the twentieth century are changing the practice of medicine. The Hippocratic Oath, for example, is no longer followed as closely as it once was. Abortions and euthanasia are performed in many areas of the world. In the U.S., the doctrine of informed consent directly conflicts with the traditional Hippocratic method of telling a patient the absolute minimum of information. [FN47] The Hippocratic Oath still remains a viable doctrine in the medical profession, but

only because the general principals of that doctrine have been adapted to fit the realities of modern medicine. As modern medicine becomes increasingly economic in nature, the underlying principals of the Hippocratic Oath can still be adapted to follow suit.

A ninth and final issue in dealing with patenting methods of medical treatment concerns the consistency of the law (both medical and patent). In most countries, medical instruments and pharmaceuticals are patentable. [FN48] Yet, in many of these same countries, methods of medical treatment are either unpatentable or patentable only with heavy restrictions. Many commentators argue that the distinction between medical instruments and pharmaceuticals, and medical methods of treatment is artificial. [FN49] One European commentator has noted that if:

... account is taken of the fact that medical equipment, pharmaceuticals and their methods of application are patentable, it is difficult to argue in favor of prohibiting patents for methods of treatment, for the former are just as much used in treatment as the latter. Indeed, they are often the actual content of the therapy. [FN50]

In the U.S., the American Medical Association's Code of Ethics once viewed the patenting of surgical instruments by physicians as unethical and derogatory to the profession. [FN51] Later, however, the AMA reversed its view by amending its Code of Ethics to allow physicians to hold patents covering surgical devices. [FN52] This reversal was based on the "... sound doctrine that one is entitled to protect one's discovery." [FN53] If surgical devices are patentable by physicians, why not medical methods of treatment? One commentator has suggested that the reasoning for the distinction may lie in the fact that development of surgical methods usually ***389** involves no capital expenditure that needs to be recaptured. [FN54] Furthermore, the risk of accidental infringement is greater, as opposed to use of instruments and pharmaceuticals, where knowledge of infringement may be discerned more readily. [FN55] Such reasoning, though persuasive, does not fully justify making surgical methods unpatentable while surgical instruments and pharmaceuticals remain patentable.

IV. PATENTABILITY OF METHODS OF MEDICAL TREATMENT IN SELECTED REGIONS OF THE WORLD.

A. Europe

The patentability of methods of medical treatment in Europe has been thoroughly analyzed due substantially to the European Patent Convention (EPC), [FN56] a wealth of interpretive European Patent Office (EPO) decisions and national case law. The EPC traces its origins to the 1973 Munich Diplomatic Conference, at which European Community members met to discuss establishing a system of granting patents valid in all member countries. [FN57] Switzerland, Sweden and Austria are now members of the convention as well. [FN58]

(1) The European Patent Convention

Article 52 of the EPC defines patentable inventions as those that are "susceptible of industrial application, which are new and which involve an inventive step." [FN59] Article 52(4) EPC then goes on to render "methods for the treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body" unpatentable by identifying such methods as not being "susceptible of industrial application." [FN60] However, Article 52(4) EPC does not apply to products (substances or compositions in particular) for use in any of the above-mentioned treatment methods. [FN61] The meaning and scope of Article 52(4) EPC has, since its inception, been well explored, mostly through EPO case law, as reviewed by its Technical Board of Appeal. It ***390** should be noted that some national courts and legislatures will interpret a transnational law, such as the EPC, more narrowly than others, resulting in different decisions on similar subject matter. [FN62] There is, however, a growing movement towards European harmonization. [FN63]

The EPC has statutorily excluded certain subject matter from being patentable in three ways: by defining certain items as "non-inventions;" [FN64] by defining others as not "susceptible of industrial application;" [FN65] and by simple, outright exclusions. [FN66] It was decided at the 1973 Munich Convention that surgical and therapeutic methods for the treatment of humans could represent independent inventions. [FN67] Indeed, the wording of Article 52(4) EPC implicitly suggests that such methods can be susceptible of industrial application. [FN68] Nonetheless, Article 52(4) EPC perpetuates the fiction that methods of medical treatment are incapable of industrial application.

In order to understand how Article 52(4) EPC operates, consideration must be given to the specific statutory language. [FN69] Article 52(4) EPC applies to three areas: surgical, therapeutic and

diagnostic methods. However, through the development of national case law and EPO decisions, Article 52(4) EPC should be examined with regard to each of the categories discussed in Section II. This is because "therapeutic" and "elective" are classifications of treatment; while "surgery" is a method of treatment. Furthermore, although the European Patents Handbook (EPH) states that methods of cosmetic treatment (a form of elective treatment) are patentable, [FN70] it also states that cosmetic surgery is not patentable. [FN71] To reconcile this dichotomy, if surgery is a method of treatment (as indicated by the subheadings in the EPH, [FN72] then it would be more precise ***391** to divide cosmetic, and to a larger extent, elective treatment into surgical and non-surgical categories. The definition of therapeutic treatment is likewise broad enough to support division into methods that are surgical and non-surgical. [FN73] The language of Article 52(4) EPC is compatible with this scheme. Applying this to Article 52(4) EPC: "[m]ethods for treatment ... by surgery [[the plain word here could be interpreted as therapeutic or elective, which are both in fact excluded according to EPO decisions [FN74]] or therapy [since surgery is already mentioned, this must necessarily imply non-surgical therapeutic methods] and ..." [FN75]

(2) The exclusionary scope of Article 52(4) EPC

In general, the scope of Article 52(4) EPC applies only to methods performed on living bodies. [FN76] Therefore, methods performed on dead bodies or amputated parts are outside the scope of Article 52 (4) EPC. [FN77] This is not true, however, if fluids taken out of the body are returned to that same person, such as with dialysis. [FN78] One commonly applied test used as a first indication of the applicability of Article 52(4) EPC is if, in view of associated health risks, a claimed treatment method has to be performed by a physician or under the guidance of a physician. [FN79] If it does, then "it will normally fall within the exclusion of the first sentence of Article 52(4) EPC." [FN80] Another test is if the treatment's objective is aimed towards the maintenance or restoration of health, in which case it will generally come under the provisions of Article 52(4) EPC. [FN81] Further tests have been developed, the use of which depends on the initial characterization of the treatment. Examining the specific language of Article 52(4) EPC, the Enlarged Board of Appeal (EPO) held the term "use" to be synonymous with "method" in finding a claim to "the use of a substance or composition for the treatment of the human or animal by therapy" not allowable. [FN82]

***392** (i) The exclusion of surgical methods

Regarding the exclusion of surgical methods, one European commentator has noted that the extraction of an organ in transplants which requires the use of an organ bank does not fall within the exclusionary scope of Article 52(4) EPC since the surgical operation is not in connection with a live body. [FN83] However, the organ extraction would fall within the scope of Article 52(4) EPC if the extracted organ immediately were then implanted in a live body. [FN84] This reasoning is supported by German case Law. [FN85]

German patent law also excludes elective surgical methods based on reasoning that many operations require special medical knowledge in order to avoid damaging a patient's health. [FN86] Similarly, British patent law disfavors elective surgical methods as exemplified by the British patent office's refusal to allow a method of embryo transplantation for mammals to be patented. [FN87] Other elective surgical methods likely to be disfavored include cosmetic surgery, the termination of pregnancy, castration, sterilization, artificial insemination and organ, skin or bone marrow removal from a living donor. [FN88]

In general, the presence of a surgical step in a multi-step method of treating human or animal bodies confers a surgical character on that method. [FN89] Thus, when deciding allowability under Article 52 (4) EPC, "... the critical question is whether there is any disclosure of a method none of whose steps fall under the prohibition of Article 52(4) EPC ...." [FN90] However, if considered in its entirety, the method includes the killing or sacrificing of the animal which is the subject of the surgery, the method will not fall within the exclusionary scope of Article 52(4) EPC. [FN91] Holding otherwise would run contrary to the purpose of Article 52(4) EPC, that is, "... to ensure that nobody who wants to use the methods specified in this article as part of the medical treatment of humans or animals should be prevented from this by patents." [FN92]

***393** (ii) The exclusion of therapeutic methods

The exclusion by Article 52(4) EPC of methods of therapeutic treatment (non-surgical) has spawned a variety of EPO decisions and national case law. Indications or tests for determining if a claimed method is an excludable therapeutic method may be used in several situations. In general, the

treatment of pain, regardless of origin, is considered a therapeutic method. [FN93] Therefore, relieving intensive headaches, [FN94] or relieving menstrual discomfort [FN95] would be excluded subject matter. For situations involving an implanted therapeutic device (for example, laser treatment of a device for refractive sight correction), if there is a functional link or "direct influence" between the method steps carried out on the device and the device's therapeutic effect on the body, then the method will be considered as a "treatment of the human body." [FN96] Not all methods for the treatment of the human or animal body, however, are excluded under Article 52(4) EPC. Elective, non-surgical treatments have been found to avoid the exclusionary scope of Article 52(4) EPC. [FN97]
A more complex situation arises when a method of treatment displays both a therapeutic and elective (i.e. cosmetic) effect. Early EPO decisions in this area favored the proposition that if the description disclosed two very different properties of a claimed compound, one resulting in a therapeutic effect and the other resulting in a non-therapeutic effect, the non-therapeutic effect was not excluded from patentability. [FN98] In a later case involving an appetite suppressant, the Technical Board of Appeal (EPO) could not draw a clear line between the cosmetic treatment of improving bodily appearance and the therapeutic treatment of curing obesity. [FN99] The Board nonetheless held the cosmetic effect patentable and judged the claims to be directed solely to the cosmetic use. [FN100] The Board in this case tried to separate the therapeutic effect from the non-therapeutic effect in order to find the non-therapeutic effect patentable. The Board did not focus on any differing properties of the ***394** compound, but rather on the effect. The decision has since been criticized by commentators [FN101] and distinguished by later decisions. [FN102]
Another case applies the properties/effects distinction more clearly. The Board's decision in T 582/88 involved a claim covering the use of an agent for increasing milk production of a ruminant. [FN103] The agent had two different properties: the non-therapeutic property of influencing fermentation in the rumen, and the therapeutic property of acting as a bactericide. Thus, two clearly distinguishable effects result: the non-therapeutic increase in milk production, and the purely therapeutic effect of an antibiotic. [FN104] This case should be contrasted with other Board decisions in that where a treatment has overlapping, indistinguishable effects that are linked with therapy, "... a claim for anything other than a second medical use is excluded from patentability." [FN105] Therefore, "[a] purely secondary effect of successful therapeutic treatment does not deprive the latter of its character as a therapeutic treatment within the meaning of Article 52(4) EPC ...." [FN106] The conclusion from this line of EPO decisions is that if a method has "... more than only a therapeutic effect, ..., then under Article 52(4) EPC it counts as an invention susceptible of industrial application within the meaning of Article 52(1) EPC, for which a patent may be granted if the usual requirements for patentability are met." [FN107] Those methods that have agents or compounds that demonstrate different properties, rather than different effects only, are more likely to receive a patent.

(iii) The exclusion of diagnostic methods
Article 52(4) EPC also excludes methods of diagnosis. [FN108] Generally, the term "diagnosis" refers to the examination leading to the identification and treatment of disease. However, diagnosis may also be performed on a body for the determination and maintenance of health. The scope of this exclusion has been well defined by EPO decisions and national case law. As currently understood, the exclusionary scope of Article ***395** 52(4) EPC covers only methods of diagnosis that: (1) are carried out on a living human or animal body; [FN109] (2) include examinations in which it is possible to immediately evaluate the results for a course of treatment; [FN110] and (3) show a "functional link" between the value measured and the treatment applied. [FN111]
For example, a physician who uses a method to collect biological samples from a patient and then evaluates those samples at a different location might infringe a patent if the particular method of diagnosis was patented. [FN112] If only intermediate results are obtained for later determination of a course of treatment, then the method is patentable. [FN113] Therefore, a method using nuclear magnetic resonance to obtain measurements (such as temperature and pH) from a body does not comprise a method of diagnosis, but merely aids an eventual diagnosis. [FN114]
There has been some divergence in a few of the national courts with regard to the second requirement. The Swiss Federal Court and the German Federal Patent Court have each extended the term "diagnostic method" to cover the examination which enables the diagnosis to be obtained. [FN115]
With regard to the "functional link" requirement, a claim directed solely to a method of measuring liquid flow through an implanted device in a body does not have a "functional link" to a method of treatment, and hence is patentable. [FN116] If a claim is directed to a method that assists an implant

in its operation, such as pressure sensors in a pacemaker, then a functional link exists and the method is excluded. [FN117]

(3) The second sentence of Article 52(4)
The second sentence of Article 52(4) EPC provides that the exclusion in the first sentence of Article 52 (4) EPC will not apply to products (such as substances or compositions) used in any of the excluded methods. Therefore, new products may be patentable regardless of whether they are used in an Article 52(4) EPC excludable method. Furthermore, already known substances and compositions may receive patent protection ***396*** as well. Article 54, which relates to the newness requirement of Article 52(1), states in part:
1. An invention shall be considered to be new if it does not form part of the state of the art.
....
5. The provisions of paragraphs 1 to 4 shall not exclude the patentability of any substance or composition, comprised in the state of the art, for use in a method referred to in Article 52, paragraph 4, provided that its use for any method referred to in that paragraph is not comprised in the state of the art.
Phrased another way, Article 54(5) EPC seems to indicate that although a compound is known, it may be patentable if the use is new. However, that new use cannot be patented! The trick then is how to patent a known compound with a new use, where the use itself is unpatentable. Three requirements become apparent: (1) there must be a compound (substance or composition), known or otherwise; (2) a medical use of the compound must be indicated; and (3) its medical use must be new. If a claim to a product satisfies the above requirements, then purpose-limited protection for a first therapeutic use may be obtained. Additionally, EPO decisions have held that protection may be obtained for all pharmaceutical uses and not just the use indicated in the claim. [FN118] As an illustration, a claim covering "a composition of formula X for treating sore throats in humans" will not be excluded if the claim represents the first therapeutic use ever disclosed for composition X. Additionally, such a claim will be considered to protect composition X for any undisclosed therapeutic uses that develop as well. Caution should be exercised when drafting claims that may be subject to Article 52(4) EPC exclusions. Within the EPC, an invention's technical features may be described by its physical entities (i.e., structure, or tangible characteristics), its physical activities (i.e., methods, or intangible characteristics), or a combination thereof. [FN119] A claim directed to an invention's physical entities is properly termed as a product claim. [FN120] A claim directed to an invention's physical activities is properly termed as a method claim. [FN121] A claim directed which includes elements ***397*** of physical entities and activities has been described as a "hybrid claim." [FN122]
Regarding hybrid claims, EPO decisions have held that none of the steps must fall under the prohibition of Article 52(4) EPC if the claim is to be held patentable. [FN123] Therefore, it would seem that hybrid claims are excluded if any elements are directed to the invention's physical activities relating to Article 52(4) EPC excludable matter. Claims drafted with functional language may escape the exclusionary scope of Article 52(4) EPC, [FN124] but an argument that the physical activities should be interpreted as functional features of an invention will likely fail. [FN125]

(4) **Swiss-type** claims
Although claims directed to methods of treatment are excluded under Article 52(4) EPC, claims directed to the "use of a substance or composition for the manufacture of a medicament for a specified new and inventive therapeutic application" (the so-called **Swiss-type** claim format) have been allowed by the EPO. [FN126] Such claims are also referred to as "second medical use" claims. **Swiss-type** claims developed as a result of the interpretation that Article 54(5) allows only purpose-limited protection for first therapeutic use, and from the pharmaceutical industry's efforts to provide protection for second and further medical uses. An example of a first medical use is a claim to a known compound in an appropriate composition suitable for administration to a patient [FN127]
The theory behind the allowability of **Swiss-type** claims is that if the claimed use is for the "manufacture" of an item, then the use is (facially) "susceptible of industrial application" within the meaning of Article 52(1) EPC. The substance or composition which is the subject of the claim may ultimately, as a practical matter, be used in a treatment which is excluded by Article 52(4) EPC. However, a claim drafted in the **Swiss-type** format restricts the substance's use to the short-term "acceptable" industrial application rather than the ultimate therapeutic use.
Despite the strangeness of the legal jargon needed to get a product use claim around the exclusionary scope of Articles 52(4) and 54 EPC, the claim format allows protection for product use

with ultimate therapeutic***398*** applications while at the same time adhering to the purpose of Article 52(4) EPC (i.e., protecting physicians from the burdens of patent infringement in non-commercial and non-industrial activities). [FN128]

Swiss-type claims have also been held allowable when other method claims have been disallowed. [FN129] As a result, **Swiss-type** claims have been regularly added in appropriate situations as a safety measure in case a later opposition invalidates other claims in a patent application.

Furthermore, the EPO has held that **Swiss-type** claims are allowable "... irrespective of the purpose (protection of a first medical use of a substance or composition [comprising the 'medicament'], or protection of a further medical use) they serve. Hence, no prior evidence of a further medical use need be submitted for this form of claim to be included in a patent application." [FN130]

To understand the utility of **Swiss-type** claims in European patent applications, consider as an example an inventor who wants to patent a method of using aspirin for the treatment of lung cancer (assuming it were possible). Before applying Article 52(4) EPC to exclude the claim, we shall examine the other requirements for patentability under Article 52(1). The determination of whether the invention is "new" (or novel) involves an added twist. Article 54(5) EPC states that a substance or composition for use in an Article 52(4) EPC method may be considered new if the use is new. Determination of the newness of the method claim would proceed, in the language of Article 54(5) EPC, as follows: "[t]he provisions of paragraphs 1 to 4 shall not exclude the patentability of any substance or composition [aspirin may be classified as such], comprised on the state of the art, [aspirin itself is old in the art] for use in a method referred to in Article 52(4), paragraph 4, [the treatment of lung cancer would be an excludable method of therapy] provided that its use for any method referred to in that paragraph is not comprised in the state of the art [assume no one else has disclosed using aspirin for treating lung cancer]." Under this analysis, the claimed method is new. Assuming an inventive step, we now consider Article 52(4) EPC. However, the claim falls within the scope of a method of therapy that is expressly excluded, and therefore, the invention is not "susceptible of industrial application," and hence does not meet all requirements for patentability under Article ***399*** 52(1) EPC. However, all is not lost. Redrafting the claim in **Swiss-type** format (use of aspirin for the manufacture of a medicament to be administered in the treatment of lung cancer) now provides a claim which should be acceptable to the EPO (assuming such treatment were possible, and the subject composition itself is not the subject of an unlicensed, still valid patent). **Swiss-type** claims are generally allowable before the EPO, but the validity of such claims varies between members of the EPC. The U.K., Sweden, Germany, and Switzerland accept the validity of **Swiss-type** claims, while the Dutch and French are more restrictive. [FN131]

The claiming of second medical uses of products (substances and compositions) to avoid the exclusionary scope of Article 52(4) EPC led some European applicants to try claiming a "second surgical use" (i.e., "use, in the manufacture of a surgical instrument for surgically treating (some bodily part) ... of a (new part or feature) ..."). The EPO Technical Board of Appeal held that such claims were not analogous to second medical use claims because the medicament of the second medical use claim will be presumably consumed, whereas the surgical instrument could be used repeatedly. [FN132] This distinction is fundamental because once the medicament has been consumed, no other uses for the medicament may be obtained. It is then easier to determine infringement if the medicament was manufactured with one purpose. A surgical instrument, on the other hand, may be manufactured with multiple purposes intended, therefore determining infringement for only one purpose when such an instrument may possess other uses becomes difficult. Additionally, the new use of a composition requires a new technical effect. [FN133] In contrast, a known device is understood not to be patentable simply because a new application has been discovered. [FN134]

Article 52(4) EPC has been criticized for perpetuating the legal fiction that methods of treatment of a body are not susceptible of industrial application. [FN135] The exclusion should have been more appropriately included as an "exception to patentability" under Article 53 EPC, or made an outright exception in national law such as Switzerland has done. [FN136] ***400*** Other possible solutions to the difficulties encountered in patenting medical methods exist as well, and will be discussed near the end of this paper.

B. United States

In contrast to the EPC, the patent laws of the U.S. regarding patentability of methods of medical treatment are very liberal. The law defining inventions patentable is contained in 35 U.S.C. § 101 "inventions patentable," which states:

[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title. [FN137]

The three basic requirements of patentability flowing from section 101 are novelty, [FN138] non-obviousness [FN139] and usefulness. [FN140] For comparison with the EPC, the U.S. invention, novelty and utility requirements loosely correspond to the new, inventive step and susceptible of industrial application requirements of Article 52(1) EPC, respectively. U.S. courts have been very liberal in deciding what constitutes patentable subject matter. Generally, "anything under the sun that is made by man" is patentable, [FN141] subject to the usual minor exceptions of printed matter, methods of doing business, purely mental steps, naturally occurring phenomena or laws of nature and mathematical formulae and algorithms. [FN142]

Regarding "use" claims, the U.S. Patent and Trademark Office (USPTO) allows "use" claims as long as the steps are recited. [FN143] A claim for a use of a composition of matter in the manufacture of a medicament, for example, will be rejected unless discrete steps are recited. [FN144] Also, claiming the use of prior art compositions will not be allowed if the use is merely directed to other properties of that composition. [FN145] However, ***401** the USPTO allows a new process of use patent in cases where the claim is not directed to a property or result. [FN146]

Regarding medical discoveries, USPTO courts have found medical and surgical methods patentable. [FN147] In the nineteenth century, however, medical and surgical methods of treatment were considered unpatentable processes because they involved the "natural functions of an animal." [FN148] This reasoning was later used to support the Commissioner of Patent's decision in Ex Parte Brinkerhoff that "the methods or modes of treatment of physicians of certain diseases are not patentable." [FN149] The Ex Parte Brinkerhoff decision was later rejected by other USPTO decisions that found that medical methods were patentable. [FN150] In the subsequent Federal district court decision of Martin v. Wyeth, the court discussed public interest concerns, noting that public interest favored wide-spread dissemination of knowledge over monopolies in the medical field. [FN151] The court then invalidated the patent under litigation, but on non-public interest reasons. [FN152] Since the Martin decision, no court has provided reasoning regarding the patentability of methods of medical treatment. Within the USPTO, medical methods are patentable. Outside the USPTO, U.S. courts still have yet to make a definitive ruling. However, the Supreme Court decision Diamond v. Chakrabarty has been pointed to as expanding the scope of patentable subject matter. [FN153]

However, the Pallin v. Singer patent infringement case involving a surgical eye procedure soon invoked a legislative response resulting in a substantial reduction in remedies available for medical method patent infringement. [FN154] In the case, one eye surgeon sued another eye surgeon over infringement of a medical method patent disclosing a new cataract surgery technique. The case was resolved after the defendant argued that the patent was invalid for lack of novelty as well as being obvious. [FN155] Nonetheless, the medical community was appalled that one physician ***402** would actually sue another over a surgical technique. The American Medical Association (AMA), among others, lobbied the U.S. Congress until a new sub-section to the patent statute was passed and signed into law by President Clinton on September 30, 1996. [FN156] The new law (a new sub-section (c) of 35 U.S.C. § 287) [FN157] came to exist as a result of a late amendment to an end-of-the-year appropriations bill, thereby bypassing the legislative channels such laws usually go through. [FN158] The procedure by which the law came to exist has been heavily criticized. Indeed, one U.S. commentator has stated that since the law was passed as an amendment to an appropriations bill, that it was valid for only one year. [FN159] This ***403** seems unlikely, as the new sub-section continues to be in the statutes, with no mention of an expiration term. [FN160]

The new subsection (c), part (1) generally eliminates infringement remedies with respect to a "medical practitioner's performance of a medical activity." [FN161] Part (2) then goes on to define the scope of part (1) by including definitions of "medical activity" [FN162] and "medical practitioner." [FN163]

35 U.S.C. § 287(c)(2)(A) provides that the elimination of remedies will not apply to a patented machine, item of manufacture, or composition of matter, biotechnological patents, and importantly, patented uses of a composition of matter. [FN164] This last exception to § 287(c) eliminates any need for **Swiss-type** claiming in the U.S. since such claiming is usually intended to provide at least some measure of protection for uses of compositions.

A thoughtful examination of § 287(c) reveals some interesting distinctions from the European patent law relating to methods of medical treatment. Perhaps the largest distinction is that the U.S. law

takes away remedies for infringement while still allowing methods of medical treatment to be patentable, while Article 52(4) EPC merely defines such methods as not being "susceptible of industrial application." Another distinction is that § 287(c)(2)(A)(ii) provides that remedies for the infringement of a patented use of a composition of matter are still available, provided (according to (c)(2)(F)) that the composition of matter in the method claim directly contributes to the "object" of the claim. The test for determining whether the hybrid claim [FN165] is exempt from (c)(1) has two steps. Step one is to determine the claim's objective, including consideration of all the process steps contained therein. [FN166] Step two is to determine "whether the steps involving the use of one or more compositions of matter either alone or in combination contribute directly to the achievement of the objective of the claimed method." [FN167]

By way of example, a claim for a method of surgery including the step of administering a novel anaesthetic will still have remedies for infringement available if the anaesthetic directly contributes to the method ***404*** of surgery. [FN168] In this sense, "first medical uses" are effective in the U.S. to the extent that physicians may incur infringement liability. In contrast, within the EPC, **Swiss-type** claiming effectively prevents physicians from incurring infringement liability. A casual comparison between the U.S. and EPC systems reveals that the pertinent EPC provision governing methods of medical treatment is facially simple to read, though drafting claims to get around it is often difficult, producing strange results (i.e., **Swiss-type** claiming). On the other hand, relevant U.S. legal text is convoluted and difficult to follow, yet careful drafting of claims to get around its restrictions need not be done to the extreme extent represented by **Swiss-type** claims.

There are other distinctions between 35 U.S.C. § 287(c) and Article 52(4) EPC. For example, 35 U.S.C. § 287(c)(2)(E) (defining the term "body") reveals that the U.S. law applies to claims covering cadavers, and therefore, the scope of 35 U.S.C. § 287(c) is not limited to living bodies, unlike Article 52(4). [FN169] Another distinction, using the same U.S. section, is that claims covering non-human animals not used in medical research are unaffected by 35 U.S.C. § 287(c)(1); i.e., veterinarians may be sued for damages resulting from patent infringement. In most EPC member states, this would not be the situation. [FN170] Also, the novel use of compositions for diagnostic purposes is considered allowable in the U.S. [FN171]

The practical effect of 35 U.S.C. § 287(c) is to eliminate infringement liability for physicians and related entities with regard to surgical procedures not involving a patented composition of matter procedure. This transforms medical method patents, in the words of one U.S. commentator, into "... a rather expensive certificate of merit." [FN172]

Despite the unorthodox manner in which § 287(c) became law, the subsection is narrowly tailored to affect the patent system only enough to accomplish its intended purpose: protection of medical practitioners from patent liability. However, in many cases, even without the new law, it is not feasible to bring an infringement action against individual physicians. Plaintiffs who bring infringement actions against individual physicians risk losing the customer good will of other physicians for a damage award that entails a higher risk of non-collection. In fact, this is ***405*** why infringement suits between physicians are relatively rare. The earlier-mentioned Pallin case has been cited as the first of its type to go to trial. [FN173] The holder of a method of medical treatment patent is more likely to obtain significant damage recovery from medical device manufactures and pharmaceutical companies. Furthermore, the new law does not limit the remedies that may be applied against such companies. Part 3 of 35 U.S.C. § 287(c) allows an action to be brought against medical device manufacturers and pharmaceutical companies on the basis of contributory infringement, or active inducement. [FN174]

Further items to note about the new law is that since patentability is not affected, any cases involving the new law will usually be decided by the U.S. Federal Courts. Even so, rights to remedies may depend on what state the infringing act occurs in since 35 U.S.C. § 287(c)(2)(B) defines a "medical practitioner" as one who is "licensed by a state [of the U.S.]." For example, one state may require a chiropractor or physical therapist to obtain a license to practice, but another state may have no such licensing requirements. If an infringing act is committed by a physical therapist in a state where licensing is not required, remedies may be sought against that individual for the infringing act.

Also, the new law does not affect trade secret protection. An inventor may still achieve limited protection for an invention through the use of trade secret law in the U.S. Trade secret law, however, is dependent on what state's law is used for protection since there is not any Federal trade secret law. Further limitations on the protections provided by trade secret law include an inability to stop independent inventors from creating or reverse-engineering an invention. [FN175]

The scope of effective claims to diagnostic methods is unclear under the new law. If a claim is drafted in such a way as to include the novel use of a composition of matter within the test parameters of 35

U.S.C. § 287(c)(2)(F), remedies may be sought against any infringer of the claim. It is unclear, though, if 35 U.S.C. § 287(c) will inhibit remedies when diagnostic methods do not include a composition of matter or a biotechnological process. For example, would a physician's use of a heart monitor machine to obtain raw data for subsequent analysis be an infringement of a patented diagnostic use of the machine that is capable of being remedied? Would it make any difference, as in Europe, if it is ***406** possible to immediately evaluate the results for a course of treatment? 35 U.S.C. § 287(c)'s silence on such matters means U.S. courts will have to determine what remedies, if any, are available for infringement of diagnostic methods.

Overall, the new law aligns the U.S. with the growing international trend towards protecting physicians from the consequences of patent infringement. The U.S. law deals with the issue by eliminating the remedies available for infringement, rather than perpetuating a legal fiction that medical inventions for treatment of humans or animals are not "susceptible of industrial application." [FN176]

The need for the new U.S. law has been questioned though. In the Pallin case, the U.S. patent system worked. The result invalidated claims to the patent at issue due to obviousness. [FN177] Also, the unorthodox manner in which the new subsection became law undermines the legitimacy behind the law. [FN178]

C. New Zealand

In contrast to the legislative battles fought in the U.S., the battles being fought in New Zealand are being waged in the courts. New Zealand's patent statute contains no express provision for excluding methods of medical treatment. Instead, courts have restricted the patentability of methods of medical treatment by determining whether such methods fall within the scope of "invention" as defined in Section 2 of the Patents Act 1953. [FN179]

Historically, both the New Zealand Patent Office and courts disfavored the patenting of methods of medical treatment. [FN180] However since the 1960s, the restrictions have loosened. For instance, the New Zealand High Court has held that methods of medical treatment involving animals are patentable. [FN181] Additionally, methods of diagnosis are patentable where the claims are clearly restricted to methods of diagnosis, and where there are no surgical steps set out in the claims. [FN182] Methods for the ***407** treatment of lice on the human body have also been held patentable, [FN183] as has a method of inhibiting bacterial growth causing toxic shock syndrome. [FN184]

In the Wellcome case, [FN185] though, the New Zealand Court of Appeals made a definitive statement on the patentability of methods of medical treatment by holding that a patent may not be granted for a method of treating a disease or illness in humans. [FN186]

In Wellcome, the Wellcome Foundation submitted an application for a method of treating meningeal leukemia in the brain by using known compounds for a new purpose, which was refused by the Assistant Commissioner of Patents as not coming within the scope of an invention under Section 2 of the Patents Act 1953. [FN187]

The Assistant Commissioner of Patent's ruling was reversed by the New Zealand High Court, Davidson, C.J., holding that there was no satisfactory basis for excluding medical methods from being patented. [FN188] The High Court's decision was subsequently reversed. [FN189] Although the Court of Appeals ruled that methods of treating human illness or disease were unpatentable, it also stated that the first therapeutic use of a known compound may receive patent protection. [FN190]

After the Wellcome case, the New Zealand Patent Office showed a reluctance to accept patent applications for the treatment of humans. However, the NZPO has since allowed claims for methods of cosmetic treatment to be patented. [FN191] Furthermore, in 1996, the New Zealand Patent Office issued a practice note that stated that claims for methods for the treatment of humans would be allowed except where the identified treatment related to surgery or to the treatment or prevention of disease. [FN192]

Later, in January 1997, the New Zealand Patent Office issued another practice note that in effect reversed an earlier decision disallowing the use of **Swiss-type** claims by stating that **Swiss-type** claims would not ***408** be refused during the examination process. [FN193] This was an attempt by the New Zealand Commissioner of Patents to put New Zealand patent examination more in line with international practice. However, not long after the Commissioner issued the practice note allowing **Swiss-type** claims, Pharmaceutical Management Agency Limited (PHARMAC) filed an action in the New Zealand High Court against the New Zealand Commissioner of Patents seeking to void the practice decision and to revoke any patents that proceeded to grant because of the practice decision. [FN194] PHARMAC manages the subsidization of pharmaceuticals in New Zealand by developing and

operating a pharmaceutical schedule. [FN195] Although the action was originally filed solely against the Commissioner of Patents, 25 international pharmaceutical companies and the Researched Medicines Industry Association of New Zealand successfully applied to be joined as co-defendants. [FN196]

A hearing was finally held in November, 1998 in the New Zealand High Court resulting in the allowability of **Swiss-type** claims. [FN197] In an opinion by Gallen, J., the court treated the case before it as an application for declaratory judgement on the patentability of **Swiss-type** claims. [FN198] Gallen distinguished the Wellcome case [FN199] by noting that the question before the Wellcome court was whether or not methods of treatment (as distinct from substances used in that treatment) were entitled to a first therapeutic use of a known substance was protectable. [FN200]

Gallen then reasoned that second medical uses were patentable as well, stating:

... indeed, Cooke J. specifically accepted that a substance intended for therapeutic use was patentable provided it was the first such use which was under consideration. If that is so, then it is difficult to see why a second and distinct use for treatment purposes, should be regarded any differently. It cannot be a question of public welfare since arguments which relate to benefits to the public apply equally to the first as to the second or any subsequent use. [FN201]

***409** Gallen next surveyed international cases, finding the European decisions especially of interest. He found the E.P.O. Case Gr. 5/83, Second Medical Use [FN202] particularly persuasive, noting that:

[t]he decision ... is relevant to the matters at present before the Court in two ways. First, it accepts that the manufacture of a medicament for a specified new therapeutic application, does not constitute a method of use of that substance or composition for the treatment of the human or animal body by therapy and therefore does not come within the prohibition on the granting of patents for such purposes. Secondly, that the novelty which is required for patentability, can be found in the manufacture for a second or subsequent therapeutic use. The enlarged Board of Appeal therefore, was able to draw a distinction between the manufacture for a use and the therapeutic use itself and to find the requisite novelty from the intended use. The case is of course not decisive of a matter arising in New Zealand. The European Patents Convention differs in working from the law as it exists in New Zealand, both in terms of development of that law through cases and in Statute. Nevertheless in so far as it involves a logical analysis, it has significance and supports the position for which the defendants contend. [FN203]

Gallen next noted that the Second Medical Use case did not run contrary to the conclusions in the Wellcome case. [FN204] He then concluded that **Swiss-type** claims were allowable in New Zealand. [FN205]

The PHARMAC case is important in that (1) it provides a well reasoned approach to the allowability of **Swiss-type** claims, and (2) it put New Zealand patent law in line with European patent law with regard to methods of medical treatment of humans.

In late 1999, the High Court's decision was unanimously affirmed by the New Zealand Court of Appeals. [FN206] In its holding, the Court found that a method of medical treatment falls within the definition of "invention," but that such claims may be properly prohibited on policy or ethical grounds. [FN207] The Court suggested that one way to make method of treatment claims in general more palatable would be to require the patentee to submit a disclaimer of any right to sue a medical practitioner, essentially the result accomplished by **Swiss-type** claims. [FN208]

***410** The New Zealand Patents Act 1953 has been under review for possible reform since 1990. [FN209] In 1992, and again in 1994, the New Zealand Ministry of Commerce published proposals for reforming New Zealand's patent statute. [FN210] Included in the report were recommendations to repeal the current definition of "invention" and to use the three criteria used in the EPC, namely, newness, inventive step and industrial applicability. [FN211] However, in contrast to the EPC, the Ministry further recommended having no exclusions. [FN212] Due to internal government changes and other delays, the proposals have yet to be acted on. [FN213]

In comparison with the patent laws of the EPC and U.S., New Zealand patent law falls somewhere in between. New Zealand allows methods of medical treatment to be patentable with respect to non-human animals, [FN214] while the EPC applies its exclusion to the treatment of animals as well. [FN215] However, New Zealand's patent law is not as liberal as the U.S. patent law, even with the addition of 35 U.S.C. § 287(c). U.S. law has no restrictions on the number of uses patentable for a known composition, save that they must not be directed to a property or result, [FN216] therefore obviating the need for **Swiss-type** claims. New Zealand law matches U.S. law in that a medical method patent covering non-human animals will be enforceable, subject to other non-medical considerations.

D. Australia

Australian patent law is in a state of uncertainty regarding the patentability of methods of medical treatment. Like New Zealand, Australia also requires that methods sought to be patented must fall within the scope of an "invention." [FN217] In 1990, Australia passed the Patents Act 1990 (hereinafter, "the 1990 Act"), which retains the definition of "invention" from the Patents Act 1952 (hereinafter, "the 1952 Act") in schedule 1 of the 1990 Act. The term "invention" as defined in Section 6 of the 1952 Act pertains to "any manner of new manufacture the subject ***411*** of letters patent and grant of privilege within Section 6 of the Statute of Monopolies, [FN218] and includes an alleged invention." [FN219] Section 6 of the Statute of Monopolies generally excludes manners of new manufacture which are contrary to the law of the state by being, among other things, "generally inconvenient." [FN220] The "generally inconvenient" language has provided courts with a way to exclude methods of medical treatment from patentability. [FN221]

In addition to retaining the definition of "invention" from the 1952 Act, the 1990 Act also contains the express exclusion that "... human beings, and the biological processes for their generation, are not patentable inventions." [FN222] However, no exclusion was included in the 1990 Act regarding patentability of methods of medical treatment. Thus far, that issue has been left to the courts to determine, which they partially did in the Anaesthetic Supplies Pty. Ltd. v. Rescare Ltd. case. [FN223] Anaesthetic Supplies concerned a method of treating snoring apnoea in a patient. Rescare sued Anaesthetic Supplies on grounds of infringement of its patent. Anaesthetic Supplies then cross-claimed on grounds that the patent was invalid for technical reasons and unpatentable because it was a method of treatment of the human body. [FN224] The case eventually reached the Full Federal Court of Australia, which held the patent invalid for technical reasons (the claims of the complete specification were not fairly based on the provisional application). [FN225] The court also considered the patentability of methods of treatment of disease in humans in general, deciding 2-1 that such methods were indeed patentable. [FN226]

The opinions of the individual justices have been intensely scrutinized by commentators. To understand the holding in Anaesthetic Supplies, older case law must be examined. The basis for the exclusion of medical patents first appeared in C & W's Application, [FN227] where the ***412*** court upheld a patent office decision not to allow an application for a method for the removal of lead from human bodies because it lacked "commercial value." [FN228] The justification presented was that the treatment had no relation to any form of manufacture or trade. [FN229] As a result, the method was not a "manner of manufacture" under Section 6 of the Statute of Monopolies 1623. [FN230] An attempt to clarify the requirement of "manner of manufacture" was later made in Re GEC's Application, [FN231] out of which the "vendible product" test was born. This test stated that:

A method or process is a manner of manufacture if it (a) results in the production of some vendible product or (b) improves or restores to its former condition a vendible product or (c) has the effect of preserving from deterioration some vendible product to which it is applied. [FN232]

Subsequently in National Research Development Corp. v. Commissioner of Patents (NRDC), [FN233] the court shifted the analysis away from the pure "manner of manufacture/vendible product" test to a more general manner of manufacture test; asking if the process or product is "... a proper subject of the letters patent according to the principles which have been developed for the application of Section 6 of the Statute of Monopolies." [FN234] To answer this inquiry in the affirmative, the subject matter must be useful, provide a material advantage, and be of value within the economic field of endeavor. [FN235] The NRDC court noted in passing the "apparent" need to exclude methods of treatment of the human body on the grounds of their "essentially non-economic" nature. [FN236]

The court in Joos v. Commissioner of Patents [FN237] narrowed the scope of the de facto exclusion of methods of treatment of the human body. [FN238] In an opinion by Barwick, C.J., the court confined the exclusion to methods of preventing or alleviating diseases, malfunctions or incapacities. [FN239] The court drew a distinction between cosmetic processes and prophylactic or therapeutic processes, noting that a cosmetic process of strengthening ***413*** hair and nails had no relation to a method of treatment of a disease, malfunction, disability or incapacity of the human body. [FN240] In so doing, the court found that the cosmetic process for improving the strength and elasticity of human hair and nails was patentable subject matter. [FN241] The court also concluded that the medical field was as economic as any other, implicitly rejecting the vendible product test as controlling. [FN242] However, the court was ambiguous as to whether an exclusion for treatment of humans actually existed. [FN243] The court's uncertain remarks prompted the Australian Industrial Property Organization (AIPO) to accept for grant patents for medical treatment methods for humans. [FN244]

Anaesthetic Supplies was the first Australian case to address the issues squarely. [FN245] In an opinion by Lockhart, J., the court substantially agreed with the reasoning articulated by Davidson, C.J., in the New Zealand Wellcome case (the New Zealand High Court decision later reversed by the New Zealand Court of Appeals). [FN246]
At the outset, Lockhart, J., recognized the patent system's encouragement of innovation, noting that:

[o]n both humanitarian an economic grounds the search for medical advance is to be encouraged. The award of limited monopolies is a standard way of helping to compensate for the expense of research. Ultimately the resolution of this question is a balancing exercise. There is on the one hand a need to encourage research in connection with methods of medical treatment and on the other hand the need not unduly to restrict the activities of those who engage in the therapy of humans. [FN247]
Lockhart further noted that other courts have excluded methods of treating the human body on the basis of "ethics rather than logic." [FN248] Lockhart underlined this point by quoting Davidson, saying that "... there was a lack of logic in any distinction which produced the result that a product for treating the human body would be patentable but not a method of treating the human body." [FN249] Later in the opinion, Lockhart expressly adopted Davidson's comments regarding the need for allowing ***414*** methods of treatment on the human body to be patentable. [FN250] He also concluded that "there is no distinction in principle between a product for treating the human body and a method of treating the human body." [FN251] He dismissed Barwick's distinctions between cosmetic and therapeutic treatment in Joos as "distinctions without a difference," noting that in Joos, the chemical resulted in a changed condition for the body. [FN252]
Lockhart then applied an adaptation of the NRDC test, stating:
[i]f a process which does not produce a new substance but nevertheless results in "a new and useful effect" so that the new result is "an artificially created state of affairs" providing economic utility, it may be considered a "manner of new manufacture" within s. 6 of the Statute of Monopolies: NRDC at 265 and 277 and Wellcome at 528. [FN253]
He further supported the court's decision by noting that the legislature had an opportunity to include an exclusion relating to methods of medical treatment in the 1990 Act, but failed to do so. [FN254]
The dissenting opinion of Sheppard J. is based on considerations of morality and public interest. [FN255] Sheppard poignantly noted that:
[i]t is not going too far, I think, to say that the Court should not contemplate the grant of letters patent which would give to one medial practitioner, or perhaps a group of medial practitioners, a monopoly over, for example, a surgical procedure which might be greatly beneficial to mankind. Its denial might mean the death or unnecessary suffering of countless people. I cannot think that this is really what the medical profession as a whole would seek to achieve. Its whole history is a denial of the proposition. [FN256]
Australian commentators have both attacked and defended Sheppard's reasoning. [FN257] However, many commentators are in agreement that the fundamental weakness in the ethics argument centers on the inconsistency of allowing patents on pharmaceuticals and instruments that can be used to treat humans while excluding methods of treating humans. [FN258] In response to the Anaesthetic Supplies decision, the AIPO amended its ***415*** Manual of Practice and Procedure to inform examiners that ethics would not be a ground of rejection. [FN259]
The Anaesthetic Supplies decision is important because it discussed many of the issues surrounding the patentability of methods of medical treatment. However, it did not directly address surgical or diagnostic methods. In fact, the decision seems to apply only to uses of compositions. So far, no major Australian case has had to deal with these issues, and the AIPO manual is silent on this area as well. The Anaesthetic Supplies decision is also interesting in that it takes a view quite different from Australia's neighbor, New Zealand, even though both countries' statutes derive from the same source and use the term "invention" as a means of defining patentability.
Although Anaesthetic Supplies addresses patentability of methods of medical treatment in detail, the justices' opinions must be considered dicta since the infringement issue under which the dispute arose was decided on other, technical grounds. [FN260] This point would become important in the next Australian case to deal squarely with the patentability issue.
After Anaesthetic Supplies, Australia became one of the most liberal patent regimes in terms of medical method patents, that is until Bristol-Myers Squibb Co. v. F.H. Faulding & Co. Ltd. [FN261] was decided. The case concerned a method of administering Paciltaxel (a naturally occurring compound from the Pacific Yew tree). [FN262] The patents involved were eventually invalidated on grounds that they lacked fair basis, novelty and inventive step. [FN263] However, the court, as per

Heerey J., also discussed whether the patents, if they had been valid, could have been infringed since they relate to methods of medical treatment. [FN264] In his analysis of the patentability issue, Heerey first noted that the discussion pertaining to the patentability of methods of medical treatment in the Anaesthetic Supplies case was dicta, and therefore non-binding. [FN265] Heerey then expressly adopted the dissenting opinion of Sheppard J. [FN266] Heerey went on ***416** to discuss ethical issues primarily concerning fear of infringement by doctors. [FN267] Heerey also noted that there was little empirical evidence for the assertion that the lack of patent protection would decrease medical research. [FN268] Heerey then proceeded to address the conflict over why patents for surgical, medical and pharmaceutical products, but not for methods of treatment, were valid. He first invoked Oliver Wendell Holme's observation that "the life of law has not been logic, it has been experience." [FN269] Heerey then concluded his discussion of the topic by quoting Cooke J. from the Wellcome case, "... there remains ... a deep-seated sense that the art of the physician or the surgeon in alleviating human suffering does not belong to the area of economic endeavour or trade or commerce." [FN270]

The Bristol-Myers case has reopened the debate in Australia concerning the patentability of methods of medical treatment. Australia now has two Federal court decisions squarely addressing the subject, but each resulting in different conclusion. It is curious to note that while Heerey J. concluded that Anaesthetic Supplies was non-binding because its conclusions on the matter were dicta, [FN271] the conclusions reached by Heerey himself were also dicta since the patents involved in the Bristol-Myers case were invalidated on the grounds as lacking fair basis, novelty and inventive step. [FN272] As a result of the Bristol-Myers decision, the Australian Patent Office has begun to allow **Swiss-type** claims. [FN273] Should the decision withstand the Court of Appeal, the Bristol-Myers case would put Australia on a similar level with New Zealand with regards to medical method patentability. It would seem that in the wake of the Bristol-Myers and PHARMAC decisions, the Australasia region is following an international trend towards putting a restriction on the patentability of method of medical treatment claims.

E. Other commonwealth regions--Canada and South Africa

The Canadian position regarding patentability of methods of medical treatment bears more resemblance to the EPC position than to Australia's. In Canada, the patent statute contains no express exclusion of ***417** methods of medical treatment. [FN274] Like New Zealand and Australia, the issue has been left to the courts to wrangle with. Accordingly, the Canadian Courts have decided that methods of medical treatment are considered inherently unpatentable. [FN275] Therefore, a method of binding wounds with a polymer is not patentable. [FN276] Additionally, prophylactic methods of treatment are unpatentable, [FN277] as are methods for reducing nicotine cravings, [FN278] and cleaning teeth. [FN279] This suggests, also, some elective methods of treatment, in particular cosmetic, are also unpatentable. However, diagnostic methods of treatment have been held to be patentable. [FN280] Also, the Canadian Federal Court of Appeal has affirmed that apparatuses designed to perform a surgical method are themselves patentable. [FN281] However, the Canadian Patent Office considers methods of using surgical instruments inherently unpatentable. [FN282]

In South Africa, the applicable patent statute includes provisions paralleling Article 52 EPC and Article 54(5) EPC, though they are worded somewhat differently. [FN283] The inclusion of provisions having the same scope as the two EPC provisions has led South Africa to adopt the use of **Swiss-type** claiming as an acceptable practice. The South African ***418** Patent Office uses what is essentially a registration/no examination system, thereby leaving the courts to decide matters of patent validity. [FN284] Thus far, no South African court has ruled **Swiss-type** claims invalid as a means of protecting use of compositions.

F. Multi-national agreements

Virtually all multinational treaties directly affecting patent rights since the 1970s make provision for signatories to voluntarily exclude methods of medical treatment from patentability. The 1970 Patent Cooperation Treaty (PCT), Rule 39.1 specifies that a designated International Searching Authority is under no obligation to conduct patent searches relating to "methods for treatment of the human or animal body by surgery or therapy, as well as diagnostic methods." [FN285] The North American Free Trade Agreement (NAFTA) Article 1709(3)(a) also allows its members to exclude from patentability "diagnostic, therapeutic and surgical methods for the treatment of humans or animals." [FN286] Similarly, Article 27:3(a) of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) allows members to exclude therapeutic, surgical and diagnostic methods from patentability.

[FN287] However, TRIPS Article 27:1 requires members to respect patent rights regardless of the technological field. In other words, discrimination against a particular field of science is prohibited in so far as exclusive patent rights are restricted. The U.S. statutory provision in 35 U.S.C. §287(c), taking away remedies for infringement of specified medical method patents, may run afoul of TRIPS Articles 44 and 45 which require members to provide remedies to address patent infringement. [FN288] For example, if an Australian citizen obtained a U.S. patent on a method of surgery, that citizen would have no remedy to pursue in an infringement action. Such a result may also violate Article 30, which permits members to have limited exceptions to their patent laws so long as those exceptions ***419** would not unreasonably conflict with the normal exploitation of a patent attempting to be enforced.

Of all the major multi-national agreements concerning patents, only the EPC has a provision whereby methods of medical treatment are excluded. [FN289]

V. SUGGESTED ALTERNATIVES RELATING TO THE PATENTABILITY OF METHODS OF MEDICAL TREATMENT

Before addressing possible alternatives, one must first consider whether methods of medical treatment should be patentable. The answer to this inquiry depends on the country and culture under consideration. If viewing the issue under a Western, property rights-based culture, patent rights become more important. However, virtually all cultures seem to recognize to at least some degree the different nature of the medical profession. The next issue is how much recognition to give to the distinction between patent and medical law. Some countries/regions have been more deliberate in their approaches to distinguishing between the two areas of law. Others have provided little, if any distinctions. If a country or region decides in favor of making methods of medical treatment patentable, then the next issue involves deciding what, if any, limitations on patentability will be used.

There is no easy alternative that will satisfy all the concerns of patent law and medical law. However, there exist ways in which the two bodies of law can coexist with less conflict. One such way is by imposing compulsory licensing on medical procedure patents. Such licensing would allow the patentee to recover research costs, encourage innovation and provide for greater consistency with other tenets of patent law which allow medical instruments to be patented. [FN290] At the same time, any problem with accessibility is eliminated, while cost is controlled and the general public interest in the physician's freedom of choice is upheld.

Compulsory licensing is already used in other areas of patent law in more than one country. In Australia, compulsory licensing may be invoked where "the reasonable requirements of the public with respect to the patented invention have not been satisfied." [FN291] Germany allows compulsory licensing in situations where a patentee may be endangering the ***420** pubic interest through abusive denial of licenses. [FN292] Similarly, the U.S. has created provisions for compulsory licensing of patents for public interest/policy reasons. For example, the U.S. Department of Agriculture has the authority to grant compulsory licenses when needed to supply "fiber, food or feed" should a patentee be so unwilling. [FN293] Also, compulsory licenses may be granted with respect to inventions beneficial to the environment. [FN294] The U.S. government may also force a patentee to grant a license to it in the biomedical research field. [FN295] The difficulty arising from using compulsory licensing lies in determining what is a reasonable royalty to be charged, if any is to be charged at all.

Another alternative is the creation and use of a "necessity doctrine." [FN296] In situations where an emergency arises and a person's life may be irreparably harmed, a necessity doctrine could be invoked allowing the physician to use the patented procedure without worry of infringement consequences. Such a doctrine flows from the notion that "one may sacrifice the personal property of another to save his life as the lives of his fellows." [FN297] However, in order to make this a viable alternative, the physician would need to become familiar with the procedure, preferably through experience.

Yet another alternative would have relevant medical bodies create and enforce rules among their members regarding applying for a patent. For example, a national physician's group could mandate that it is unethical for a physician to seek a surgical process patent. Rules could also be created to simply disfavor patenting of methods of medical treatment, or mandate an allocation of a certain percentage of royalties to medical research. The difficulty arising from this approach involves effective enforcement of rules among members.

Another means of balancing patent and medical law interests would be to legislate a reduction in patent terms for certain classes of invention. For example, with surgical procedures, a legislative body

might find that a patent term of ten years is appropriate to recover any research costs. Along the same lines, term extensions could be eliminated. However, as one commentator has noted, these options will not really solve the underlying ***421** problems of infringement risks, but merely mitigate the problems through use of a shorter time frame. [FN298]

Prior user rights could be invoked as a defense in those countries that recognize such rights. Prior user rights essentially provide a strengthened form of trade secret protection. Under this regime, a prior user would be safe from infringement liability of a subsequent patent holder of a common method of medical treatment. [FN299] However, one who invokes prior user rights may encounter substantial difficulties in proving prior use. So far, though, this defense has not been utilized much. [FN300]

One commentator has proposed legislating the use of a four-prong patentability test. [FN301] Under this test, four elements of patentability must be met for methods of medical treatment. In addition to novelty, non-obviousness and utility (or if under the EPC, newness, inventive step and industrial application), one would also have to demonstrate that the method's development required substantial research and development expenditures. [FN302] Of course, "substantial research and development expenditures" may need more definition. It has been proposed that a fixed monetary floor be established to assist with what is "substantial" and what is not. [FN303] This alternative has the advantage of allowing patentees to recover development costs, and therefore promote innovation, while at the same time disallowing methods of surgical treatment which may involve little development cost and implicate more ethical concerns.

A final alternative would be to provide no restrictions/exclusions on the patenting of methods of medical treatment. It could be argued that if left to itself, the patent system will work to ensure that only new and useful inventions will be protected. In the Pallin surgical patent infringement case that brought about 35 U.S.C. § 287(c), the relevant portions of the patent were declared invalid and unenforceable. Outside of this case, the U.S. does not seem to have suffered any disastrous effects from allowing medical method patents. Likewise, in Australia there seems to be little evidence showing that the medical profession is suffering heavily due to the existence of medical method patents. Also, an Australian court found a medical method patent unenforceable for technical reasons, [FN304] ***422** thereby showing that the patent system can apply to medical method patents. Therefore, eliminating any restrictions on patenting of methods of medical treatment should also be considered a viable option.

None of the above options provide the "ideal solution," however compulsory licensing seems to provide the best balance in addressing most of the patent/medical considerations. Many people will acknowledge the "special nature" of the medical profession, and as a result, accord it some form of special consideration. The extent of any special consideration is ultimately up to each country or region.

VI. CONCLUSION

The patentability of methods of medical treatment encompasses two different areas of law: patent and medical. Just where the balance is to be struck between the two largely depends on numerous ethical and economic issues. Some patent regimes have chosen to impose statutory restrictions, while others have judicially applied restrictions. Also, the scope of restrictions regarding patentability varies between a complete absence of restrictions to restrictions covering virtually all forms of treatment on both humans and animals. In the end, the question that must be answered is "what is the best way to improve the level of medical care?" If it is believed that economic incentive will encourage innovation to improve the level of medical knowledge, then a patent law regime will dominate. If, on the other hand, it is believed that medical knowledge is expanded with speed and efficiency through open sharing among those in the medical profession, then a medical regime will exert a heavy influence. There is no easy, clear solution that will satisfy the needs of both areas of law. Each patent regime must strike a balance by weighing all the ethical factors considered important to that society. This balancing process is more visible in patent regimes where the issue is decided judicially, such as in Australia and New Zealand.

There is an apparent recognition within the global patent community that some medical method inventions are more ethically justifiable to exclude. For instance, a method of therapeutic surgery generally involves little in the way of research expenditures, nor is such a method usually invented with the goal of obtaining patent rights. At the same time, such methods may be highly decisive in preventing irreparable harm to a patient in a moment of emergency. In this instance, the balance shifts towards medical law, and the next quest is to find an appropriate solution, such as compulsory

licensing. At the other end of the justification scale lies claims to methods of using a composition. Justification for ***423** excluding these types of claims is weaker since such claims usually involve a product that is not re-used, and there are usually acceptable alternatives available that will not significantly effect a patient's life in a time of emergency.
Whether one chooses to ignore them or not, ethical issues will play a role in defining the patentability of methods of medical treatment. Indeed, as several Australian judges and European commentators have noted, any reason for excluding methods of medical treatment appear to be based on ethics rather than logic. [FN305] Such an exercise in ethical considerations will assist with subsequent patent-medical law issues such as the cloning of humans. This will in turn lead to a better, more well reasoned law.

[FNa1]. Chantilly, VA

[FN1]. See generally, Doris Thums, Patent Protection for Medical Treatment-- A Distinction Between Patent and Medical Law, 27 IIC 423, 426 (1996).

[FN2]. For more on the background of patents generally, see 1 Donald S. Chisum, Patents § 1.01 (1995).

[FN3]. Joel J. Garris, The Case for Patenting Medical Procedures, 22 Am. J. L. and Med. 85, 93 (1996).

[FN4]. See generally, Thums, supra note 1, at 426.

[FN5]. See, e.g., Case T 780/89, Immunostimulant, 1993 O.J. EPO 440, 25 IIC 82 (1994)

[FN6]. Some jurisdictions exclude animals. See, e.g., Article 52(4) European Patent Convention (Munich 1973).

[FN7]. Case T 19/86, Pigs II/Duphar, 1989 O.J. EPO 24, 20 IIC 196 (1989).

[FN8]. Case T 24/91, Cornea, 1995 O.J. EPO 512, 27 IIC 530 (1996).

[FN9]. Id.

[FN10]. Rainer Moufang, Methods of Medical Treatment Under Patent Law, 24 IIC 18, 37 (1993); excellent definitions of "surgery" are further contained in Case T 182/90, Blood Flow, 1994 O.J. EPO 641, 26 IIC 87 (1995).

[FN11]. Elective treatment may therefore include "cosmetic treatment, the termination of pregnancy, castration, sterilization, artificial insemination, embryo transplants, treatments for experimental and research purposes and the removal of organs, skin or bone marrow from a living donor." Case T 182/90, Blood Flow, supra note 10 (describing the term "medical treatment").

[FN12]. Thums, supra note 1, at 428.

[FN13]. Rainer Moufang, supra note 10, at 45.

[FN14]. Brian McCormick, Just Reward or Just plain Wrong? The Specter of Royalties From Method Patents Stirs Debate, 37 Am. Med. News 3, 3 (September 5, 1994).

[FN15]. See generally, Chisum, supra note 2.

[FN16]. Ethical Issues in the Patenting of Medical Procedures, American Medical Association, Council on Ethical and Judicial Affairs, Code of Medical Ethics Volume VI, Number 2 (July, 1995), at 66.

[FN17]. Patricia Loughlan, Of Patents and Patients: New Monopolies in Medical Methods, Australian Intellectual Property Journal 5, 13 (1995).

[FN18]. Gregory F. Burch, Ethical Considerations in the Patenting of Medical Processes, 65 Texas L REV 1139, 1143 (1987)).

[FN19]. William D. Noonan, Patenting Medical and Surgical Procedures, 77 J. Pat. & Trademark Off. Soc'y 651, at 656-657 (1995)).

[FN20]. Id.

[FN21]. Many medical research projects aimed at non-life threatning treatments are privately financed with the hope that a profit will eventually be realized. See generally, Garris, supra note 3, at 92.

[FN22]. Id.

[FN23]. See, e.g., Wendy W. Yang, Patent Policy and Medical Procedure Patents: The Case for Statutory Exclusion From Patentability, 1 B.U. J. SCI. & TECH. L. 5, head note 39 (1995), and Loughlan, supra note 17, at 13.

[FN24]. See, e.g., Patent Cooperation Treaty (PCT) (Washington, 1970), Article 21(2)(a).

[FN25]. See, e.g., 35 U.S.C. § 102 (1994) (U.S.) which generally focuses on events before an application date to defeat novelty. See also, Article 54(2) European Patent Convention (Munich 1973) ("[t]he state of the art shall be held to comprise everything made available to the public ... before the filing date of the European patent application").

[FN26]. See, e.g., 35 U.S.C. § 101 (1994) (U.S.).

[FN27]. See generally, McCormick, supra note 14, at 3.

[FN28]. See, e.g., Garris, supra note 3, at 97.

[FN29]. Id. at 92.

[FN30]. Linda Rabin Judge, Issues Surrounding the Patenting of Medical Procedures, 13 Computer & High Tech. L.J. 181, 201 (1997).

[FN31]. Anaesthetic Supplies Pty. Ltd. v Rescare Ltd., 122 ALR 141, 28 IPR 383, at 421 (1994) (Austl. Fed. Ct.).

[FN32]. See Garris, supra note 10, at n.77.

[FN33]. Loughlan, supra note 17, at 14; see also, Lara L. Douglass, Medical Process Patents: Can We Live Without Them? Should We?, 3 J. Intell. Prop. L. 161, 179 (1995) (examples of conflicts of interest given).

[FN34]. Bradley J. Meier, The New Patent Infringement Liability Exception For Medical Procedures, 23 J. Legis. 265, 267 (1997).

[FN35]. Id.

[FN36]. Id.

[FN37]. Garris, supra note 3, at 99.

[FN38]. Id.

[FN39]. Beata Gocyk-Farber, Patenting Medial Procedures: A Search for a Compromise Between

Ethics and Economics, 18 Cardoza L. Rev. 1527, 1546-1547 (1997).

[FN40]. Yang, supra note23, at head note 28.

[FN41]. Garris, supra note 3, at 98.

[FN42]. Philip Culbert, Patent Law Reform in New Zealand: Should Methods of Medical Treatment be Patentable?, Patent World, May, 1997, at 32, 37.

[FN43]. Judge, supra note 30, at 203.

[FN44]. Loughlan, supra note 17, at 15.

[FN45]. Yang, supra note 23, at head note 24.

[FN46]. Garris, supra note 3, at 93.

[FN47]. Id. at 94.

[FN48]. In fact, no major patent regime covered in this paper denies patents based on a classification as medical instrument.

[FN49]. See, e.g., Judge, supra note 30, at 198.

[FN50]. Thums, supra note 1, at 440.

[FN51]. Garris, supra note 3, at 5, n.103.

[FN52]. Id. at 95.

[FN53]. Id. at 94, (quoting from 1992 Code of Medical Ethics: Annotated Current Opinions of the Council on Ethical and Judicial Affairs of the American Medical Association 9.09 (1992)).

[FN54]. Culbert, supra note 42, at 38.

[FN55]. Id.

[FN56]. European Patent Convention (EPC) (Munich 1973).

[FN57]. Akim F. Czmus, Biotechnology Protection in Japan, European Community, and the United States, 8 Temp. Int'l & Comp. L.J. 435, 437 (1994).

[FN58]. Id. at 441.

[FN59]. Article 52(1) EPC.

[FN60]. Id.

[FN61]. Id.

[FN62]. For example, in Austria veterinary medical methods are not excluded. Moufang, supra note 10, at 30, n.63.

[FN63]. See, e.g., Case T 780/89, Immunostimulant, supra note 5, at 85, point 4.

[FN64]. Article 52(2) EPC.

[FN65]. Article 52(4) EPC.

[FN66]. Article 53 EPC.

[FN67]. Thums, supra note 1, at 424, n.12.

[FN68]. Case T 182/90, Blood Flow, supra note 10, at 88, point 2.1, 2nd paragraph. (The Board hints that such methods may, in fact, be susceptible of industrial application). See also, Moufang, supra note 10, at 32.

[FN69]. Article 52(4) EPC states:
(4) Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body shall not be regarded as inventions which are susceptible of industrial application within the meaning of paragraph 1. This provision shall not apply to products, in particular substances or compositions, for use in any of these methods.

[FN70]. European Patents Handbook (EPH), (2nd edn.) Rel 24 (1996), point 3.5.3(B), p. 3/14.

[FN71]. Id. at point 3.5.2, p. 3/12.

[FN72]. See, e.g., EPH, supra note 70, point 3.5.2(A), p. 3/12.

[FN73]. See Section II, supra for these definitions.

[FN74]. See, e.g., Case T 182/90, Blood Flow, supra note 10, at 89, point 2.4 (the Board acknowledges the capacity of "surgery" to apply to both curative and elective (i.e., cosmetic) situations).

[FN75]. Article 52(4) EPC.

[FN76]. Case T 182/90, Blood Flow, supra note 10, at 88, point 2.1.

[FN77]. Moufang, supra note 10, at 36.

[FN78]. Id. at 41.

[FN79]. Case T 24/91, Cornea, supra note 8, at 532, point 2.4.

[FN80]. Id.

[FN81]. Case T 19/86, Pigs II/Duphar, supra note 7 (the Board found a claim having as its objective the maintenance or restoration of health, thereby coming within the provision of Article 52(4) EPC).

[FN82]. Case Gr. 5/83, Second Medical Use, 1985 O.J. EPO 64, 16 IIC 83 (1985) (EPO Enlarged Tech. Bd. Of App.).

[FN83]. Moufang, supra note 10, at 38.

[FN84]. Id.

[FN85]. See Moufang, supra note 10, at 38, n.113 for examples of such German case law.

[FN86]. Implantreren Von Haarbundeln, 30 BpatGE 134, December 12, 1988 (German Fed. Pat. Ct.).

[FN87]. Decision of March 5, 1984, Occidental Petroleum Corporation's Application, 16 IIC 216 (1985) (British Pat. Off.).

[FN88]. Case T 182/90, Blood Flow, supra note 10, at 88, point 2.2.

[FN89]. Id. at 90, point 2.5.1.

[FN90]. Case T 820/92, point 5.5, 1995 O.J. EPO 113, 26 IIC 543 (1995).

[FN91]. Case T 182/90, Blood Flow, supra note 10, at 90, point 2.5.2.

[FN92]. Case T 24/91, Cornea, supra note 8, at 532, point 2.4.

[FN93]. Case T 81/84, Dysmenorrhea/Rorer, 1988 O.J. EPO 207, 19 IIC 803 (1988).

[FN94]. Id.

[FN95]. Id.

[FN96]. Case T 24/91, Cornea, supra note 8, at 532, point 2.6.

[FN97]. For example, EPH, supra note 70, point 3.5.3(B) states that "methods of cosmetic treatment are not excluded from patentability."

[FN98]. Case T 780/89, Immunostimulant, supra note 5, at 83, point 3.1, (summarizing the Board's decision in T36/83).

[FN99]. Case T 144/83, Appetite Suppressant/Dupont, 1986 O.J. EPO 301, 18 IIC 258 (1987).

[FN100]. Id.

[FN101]. See, e.g., Moufang, supra note 10, at 43.

[FN102]. See, e.g., Case T 290/86, Cleaning Plaque/ICI, 1992 O.J. EPO 414, 23 IIC 815 (1992).

[FN103]. Case T 582/88 (unreported, but summarized in 1991 O.J. EPO 19).

[FN104]. Id.

[FN105]. Case T 290/86, Cleaning Plaque/ICI, supra note 102.

[FN106]. Case T 780/89, Immunostimulant, supra note 5, at 85, point 7, (applicants argued that non-therapeutic use of the "imminostimulation" agent increased meat production, but the Board found that this result derived from the prophylactic treatment of diseases and improved the health of the subject, and therefore found the method claim unpatentable).

[FN107]. Id. at 84, point 4.

[FN108]. Article 52(4) EPC.

[FN109]. Case T 385/86, Non-invasive Measurement, 1988 O.J. EPO 308, 20 IIC 75, point 3.2 (1989).

[FN110]. Id.

[FN111]. Case T 245/87, Flow Measurement/Siemens, 1989 O.J. EPO 171, 20 IIC 878 (1989).

[FN112]. See, e.g., Diagnostizierverfahren, 1985 GRUR 278, 279 (German Fed. Pat. Ct.).

[FN113]. Id.

[FN114]. Id.

[FN115]. 108 BGE II 221 Decision of September 21, 1982 (Swiss Fed. Ct.); Diagnostizierverfahren, supra note 103.

[FN116]. Case T 245/87, Flow Measurement/Siemens, supra note 111.

[FN117]. Case T 82/93, Cardiac Pacing, 1996 O.J. EPO 274, 28 IIC 90 (1997).

[FN118]. See, e.g., Case T 128/82, Pyrrolidine Derivatives/Hoffmann-La Roche, 1984 O.J. EPO 174, 15 IIC 520 (1984)

[FN119]. Id. at 93, point 1.3.

[FN120]. Id.

[FN121]. Id.

[FN122]. Case T 82/93, Cardiac Pacing, supra note 117, at 93, point 1.3.

[FN123]. Case T 128/82, Pyrrolidine Derivatives/Hoffmann-La Roche, supra note 118, at point 1.4.

[FN124]. See, e.g., Case T 426/89, Pacemaker/Siemens, 1992 O.J. EPO 172, 23 IIC 523 (1992).

[FN125]. See, e.g., Case T 82/93, Cardiac Pacing, supra note 117, at 94, point 1.5.

[FN126]. Case Gr. 5/83, Second Medical Use, supra note 82.

[FN127]. See generally, J. Savina, The Patentability of the Second Therapeutic Application--Why must the Law be Changed?, Patent World, August, 1995, at 32.

[FN128]. See, e.g., Case T 24/91, Cornea, supra note 8; and Case Gr. 5/83, Second Medical Use, supra note 82.

[FN129]. See, e.g., Case T 290/86, Cleaning Plaque/ICI, supra note 102; and Case T 144/83, Appetite Suppressant/Du Pont, supra note 99 (two examples of cases where the Board found all method claims invalid except the Swiss-style claims).

[FN130]. Case T 143/94, Trigonelline, 1996 O.J. EPO 430, 28 IIC 95, 96, point 3.2 (1997).

[FN131]. EPH, supra note 70, at point 3.5.3(A), p. 3/14.

[FN132]. Decision of the Technical Board of Appeal, Case T 227/91 (as mentioned in the EPH, supra note 70, point 3.5.2(B)).

[FN133]. Rule 29(1) EPC requires claims to "define the matter for which protection is sought in terms of the technical features of the invention." Id.

[FN134]. EPH, supra note 70, at point 3.5.2(B), p. 3/13.

[FN135]. For more commentary concerning the "legal fiction," see generally, Moufang, supra note 10, at 33-35; Thums, supra note 1, at 424; and Savina, supra note 127, at 32.

[FN136]. Moufang, supra note 10, at 30, n.67.

[FN137]. 35 U.S.C. § 101 (1994) (U.S.).

[FN138]. 35 U.S.C. § 102 (1994) (U.S.).

[FN139]. 35 U.S.C. § 103 (1994) (U.S.).

[FN140]. 35 U.S.C. § 101 (1994) (U.S.).

[FN141]. Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980) (The Court held that genetically engineered microorganisms are patentable subject matter)

[FN142]. Application of Chatfield, Cust. & Pat. Appl. 1926, 545 F.2d 152, Cert. Denied 434 U.S. 875 (1926).

[FN143]. Manual of Patents and Examining Procedure (MPEP), 7th ed. (December, 1997), (rev'd. July, 1998), at § 2173.05q.

[FN144]. Id.

[FN145]. Id. at § 2112.01. As an illustration, the MPEP mentions the case In Re May, 197 U.S.P.Q. 601, 607 (CCPA 1978), in which two claims directed to a method of effecting non-addictive analgesia (pain reduction) in animals were found to be anticipated by prior art that disclosed the same compounds for effecting analgesia, but was silent as to addiction. The court went on to hold that the applicants merely discovered a new property of the compound, and as such, was not a new use. MPEP, at § 2112.02.

[FN146]. Id. at § 2112.02. See also, In Re Huck, 114 U.S.P.Q. 161, 163 (CCPA 1957).

[FN147]. Ex Parte Scherer, 103 U.S.P.Q. (BNA) 107, 110 (Pat. Off. Bd. App. 1954);

[FN148]. Morton v. New York Eye Infirmary, 17 Fed. Cas. 879, 884 (S.D.N.Y. 1862) (No. 9,865).

[FN149]. Ex Parte Brinkerhoff, 24 Off. Gaz. Pat. Office 349 (Comm'r Pat. Office 1883) (the Commissioner of Patents rejected an application for the treatment of hemorrhoids).

[FN150]. Ex Parte Scherer, supra note 139.

[FN151]. Martin v. Wyeth, Inc., O.C. Md. 1951, 96 F. Supp. 689, Affm'd 193 F.2d 58 (Patent for a method of administering a medicine for treating mastitis invalidated).

[FN152]. Id.

[FN153]. Diamond v. Chakrabarty, supra note 141.

[FN154]. Pallin v. Singer, 36 U.S.P.Q.2d (BNA) 1050 (1995).

[FN155]. Id.

[FN156]. The Omnibus Consolidated Appropriations Act of 1997, Pub. L. No. 104-208, 110 Stat. 3009 (1996).

[FN157]. Parts one and two of the new law, sub-section (c) of 35 U.S.C. § 287 are as follows:
(c)(1) With respect to a medical practitioner's performance of a medical activity that constitutes an infringement under section 271(a) or (b) of this title, the provisions of sections 281, 283, 284, and 285 of this title [which relate to the remedies of injunction, damages and attorney fees] shall not apply against the medical practitioner or against a related health care entity with respect to such medical activity.
(2) For the purpose of this subsection:
(A) the term "medical activity" means the performance of a medical or surgical procedure on a body, but shall not include (I) the use of a patented machine, manufacture, or composition of matter in violation of such patent, (ii) the practice of a patented use of a composition of matter in violation of such patent, or (iii) the practice of a process in violation of a biotechnology patent.
(B) The term "medical practitioner" means any natural person who is licensed by a State to provide

the medical activity described in subsection (c)(1) or who is acting under the direction of such person in the performance of the medical activity.
(C) The term "related health care entity" shall mean an entity with which a medical practitioner has a professional affiliation under which the medical practitioner performs the medical activity, including but not limited to a nursing home, hospital, university, medical school, health maintenance organization, group medical practice, or a medical clinic.
(D) The term "professional affiliation" shall mean staff privileges, medical staff membership, employment or contractual relationship, partnership or ownership interest, academic appointment, or other affiliation under which a medical practitioner provides the medical activity on behalf of, or in association with, the health care entity.
(E) The term "body" shall mean a human body, organ or cadaver, or a non-human animal used in medical research or instruction directly relating to the treatment of humans.
(F) The term "patented use of a composition of matter" does not include a claim for a method of performing a medical or surgical procedure on a body that recites the use of a composition of matter where the use of that composition of matter does not directly contribute to achievement of the objective of the claimed method.
(G) The term "State" shall mean any state or territory of the United States, the District of Columbia, and the Commonwealth of Puerto Rico.

[FN158]. Normally before a legislative bill becomes law, the bill will be debated or discussed in one or more Congressional committees. By adding the amendment to an appropriations bill, the amendment by-passed the usual committee hearings. See generally, Meier, supra note 34, at 275.

[FN159]. Judge, supra note 30, at 190.

[FN160]. See 35 U.S.C.A. § 281(c) (1997 supplement) (U.S.).

[FN161]. Id.

[FN162]. Id. at (2)(A).

[FN163]. Id. at (2)(B).

[FN164]. Id.

[FN165]. See Section IV(A)(3), supra.

[FN166]. In the U.S., "use" claims need to recite steps, MPEP, supra note 143, at § 2173q.

[FN167]. H.R. Conf. Rep. No. 104-863, at 852-55 (1996), (Congressional legislative history of § 287 (c)).

[FN168]. Id.

[FN169]. See Section IV(A), supra.

[FN170]. But see, note 62, supra.

[FN171]. H.R. Conf. Rep. No. 104-863, at 852-55 (1996).

[FN172]. Michael W. Garvey, New Medical-Procedure Patents Can't Be Infringed The Intellectual Property Strategist, December, 1996 at 5.

[FN173]. McCormick, supra note 14.

[FN174]. Randall B. Bateman and M. Wayne Western, Medical Procedure Patents, The 1996 Amendment And Who Is Really Liable, Intellectual Property Today, December, 1997, at 6, 34.

[FN175]. Chris J. Katopis, Patients v. Patents?: Policy Implications of Recent Patent Legislation, 71 St. John's L. Rev. 329, 345 (1997).

[FN176]. Article 52(4) EPC.

[FN177]. Pallin, supra note 154, at 1053.

[FN178]. See note 158, supra.

[FN179]. Patents Act 1953 § 2 (N.Z.) defines "invention" to mean "... any manner of new manufacture the subject of letters patent and grant of privilege within Section 6 of the Statute of Monopolies and any new method or process of testing applicable to the improvement or control of manufacture; and includes an alleged invention."

[FN180]. Tom Syddall, Method of Treatment Claims and Patent Law Reform in New Zealand, CIPA Journal, June, 1996, at 423.

[FN181]. Swift & Company's Application, [1960] NZLR 775, [1961] RPC 129, [[[1962] RPC 37 (D.C.) (N.Z. H.C. (formally S.Ct.)).

[FN182]. Bio-Digital Sciences Incorporated's Applications [1973] RPC 668 (N.Z. Pat. Off.).

[FN183]. Stafford-Miller Ltd.'s Applications [1984] FSR 258 (N.Z. Pat. Off.).

[FN184]. Office Practice Note--Methods of treatment of Humans, NZPOJ No. 1402, Vol. 85, Issue No. 2 (26 March 1996).

[FN185]. The Wellcome Foundation Ltd. v. Commissioner of Patents [1983] FSR 593, [1983] NZLR 385 (N.Z. Ct. App.).

[FN186]. Id.

[FN187]. Wellcome Foundation Ltd. (Hitching's) Application [1978] FSR 51 (NZ Pat. Off.).

[FN188]. Wellcome Foundation Ltd. (Hitching's) Application, [1979] 2 NZLR 591, [1980] RPC 305.

[FN189]. Wellcome, supra note 185.

[FN190]. Id. at 383.

[FN191]. Joseph Handelman's Application, NZPOJ No. 1367, Vol. 82, Issue No. 3 (23 April 1993).

[FN192]. Office Practice Note-Methods of Treatment of Humans, Supra note 184.

[FN193]. Office Practice Note--'**Swiss' Type** patent claims, NZPOJ No. 1412, Vol. 85, Issue No. 12 (29 January 1997).

[FN194]. Michael Hawkins, "**Swiss" Type** Patent Claims on Hold, Patent World, September, 1997, at 8.

[FN195]. Tom Syddall, **Swiss-Type** Claims in New Zealand, CIPA Journal, July, 1997 at 546.

[FN196]. Hawkins, supra note 194.

[FN197]. Pharmaceutical Management Agency Ltd. v. The Commissioner of Patents, CP. 141/97, 17 December 1998 (N.Z. H.C.) (still unpublished at the time of writing of this paper).

[FN198]. Id. at page 36 of the opinion.

[FN199]. Wellcome, supra note 185.

[FN200]. PHARMAC, supra note 197, at 15.

[FN201]. Id., at 20.

[FN202]. Case Gr. 5/83, Second Medical Use, supra note 82.

[FN203]. PHARMAC, supra note 197, at 28.

[FN204]. Id., at 31.

[FN205]. Id., at 35.

[FN206]. Pharmaceutical Management Agency, Ltd. v. The Commissioner of Patents, CA 56/99, 17 December 1999 (N.Z. Ct. App.).

[FN207]. Greg Arthur, **Swiss-Type** Claims Held Valid in New Zealand, information flash available at the A.J. Park & Son web site (http:// www.ajpark.co.nz), visited April 23, 2000; See also, CIPA Journal, January, 2000.

[FN208]. Id.

[FN209]. Culbert, supra note 42, at 33.

[FN210]. Id. at 32-33.

[FN211]. Id.

[FN212]. Id.

[FN213]. Tom Syddall, **Swiss-type** Use Claims Now Allowed in New Zealand, CIPA Journal, 138, 140 February, 1997, at 138, 140.

[FN214]. Swift, supra note 181.

[FN215]. Article 52(4) EPC.

[FN216]. MPEP, supra note 143, at § 2112.02

[FN217]. Patents Act 1990, § 18(1) (Austl.)

[FN218]. Statute of Monopolies, 21 Jac. 1, ch. 3 (1623), which is derived from British law, states in part:
"... provided also, and be it declared and enacted, that any declaration before-mentioned shall not extend to any letters patent and grants of privilege for the term of 14 years or under, hereunder to be made, on the sole working or making of any manner of new manufactures within its realm, ..."

[FN219]. Patents Act 1952, § 6 (repealed) (Austl.).

[FN220]. Statute of Monopolies, supra note 218.

[FN221]. See, e.g., Joos v. Commissioner of Patents, 126 CLR 611 (1972) (Austl.).

[FN222]. Patents Act 1990 § 18(2) (Austl.).

[FN223]. Anaesthetic Supplies Pty. Ltd. v. Rescare Ltd., 122 ALR 141 (1994) (Lockhart, Wilcox,

Sheppard J.) (Austl. Fed. Ct.).

[FN224]. Id.

[FN225]. Id. at 142.

[FN226]. Id. at 141.

[FN227]. C & W's Application, 31 RPC 235 (1914) (Austl.).

[FN228]. Id. at 236.

[FN229]. Id.

[FN230]. Id.

[FN231]. Re GEC's Application, 60 RPC 1 (1942) (Austl.).

[FN232]. Id.

[FN233]. National Research Development Corp. v. Commissioner of Patents, 102 CLR 252 (1959), [1960] ALR 114, [1961] RPC 134 (Full Ct. of the H.Ct., Austl.).

[FN234]. Id. at 269.

[FN235]. Id. at 275.

[FN236]. Id. at 270, 275.

[FN237]. Joos, supra note 221.

[FN238]. Up to this point, no Australian Court expressly acknowledged the existence of an exclusion.

[FN239]. David Kell, Expanding the Frontier of Patentability: Methods of Medical Treatment of the Human Body, [1995] 4 EIPR 202, at 203.

[FN240]. Joos, supra note 221, at 623.

[FN241]. Id.

[FN242]. Id. at 618.

[FN243]. Kell, supra note 239, at 203.

[FN244]. Australian Industrial Property Organization, Patent Office, Manual of Practice and Procedure, Vol. 2 § 8.1.14.4 (1994).

[FN245]. Up to that point, there was still no express exclusion in statute or case law.

[FN246]. Wellcome, supra note 188.

[FN247]. Anaesthetic Supplies, supra note 223, at 153.

[FN248]. Id.

[FN249]. Id.

[FN250]. Id.

[FN251]. Id.

[FN252]. Id.

[FN253]. Id. at 154.

[FN254]. Id.

[FN255]. Kell, supra note 239, at 204.

[FN256]. Anaesthetic Supplies, supra note 223, at 170.

[FN257]. See, e.g., Loughlan, supra note 17, and Kell, supra note 239.

[FN258]. See, e.g., Kell, supra note 239, Loughlan, supra note 17, and Culbert, supra note 42; see also Section III, supra.

[FN259]. Australian Industrial Property Organization, Patent Office, Manual of Practice and Procedure, at § 8.5.2 (1994).

[FN260]. Indeed, the court held the patent invalid, thereby finding no infringement. Nonetheless, all three justices addressed the issue of whether methods of treatment of humans were patentable despite the fact that any findings from such an investigation would have no hearing on the case under consideration.

[FN261]. Bristol-Myers Squibb Co. v. F.H. Faulding & Co. Ltd., No. VG 109 of 1995, 22 July 1998 (Austl. Fed. Ct.) (unpublished, but available at the Phillips, Ormonde & Fitzpatrick web site (http://www.pof.com.au), visited April 23, 2000).

[FN262]. Id. at page 6 of the decision.

[FN263]. Id. at 30.

[FN264]. Id. at 24, 25.

[FN265]. Id. at 21.

[FN266]. See pg. 36 supra for a portion of this text.

[FN267]. Bristol-Myers, supra note 261, at 24.

[FN268]. Id. at 25.

[FN269]. Id. at 25.

[FN270]. Wellcome, supra note 185, at 388.

[FN271]. Bristol-Myers, supra note 261, at 21.

[FN272]. Id. at 30.

[FN273]. Traditionally, **Swiss-type** claims were rejected for lack of clarity. See Phillips, Ormonde & Fitzpatrick Australian Update, Nov., 1998; available online at: http://www.pof.com.au.

[FN274]. Patents Act § 39(1) (1995) (Can.)

[FN275]. Tennessee Eastman Co. v. Commissioner of Patents, 8 C.P.R. (2d) 202 (1972) (S.C.C.,

Can.).

[FN276]. Id.

[FN277]. Re Application of Ackerman, 105 C.P.O.R. 14-xviii (1977) (Can.).

[FN278]. Re Application of Revici, 71 C.P.R. (2d) 285 (1981) (Can. Comm'r Pat.).

[FN279]. Imperial Chemical Ltd. v. Commissioner of Patents, 9 C.P.R. (3d) 289 (FCA) (1986) (Can. Fed. Ct.).

[FN280]. Re Application for patent of Goldenberg, 22 C.P.R. 159 (1988) (Can. Comm'r Pat.).

[FN281]. Visx, Inc. v. Nidek Co., 72 C.P.R. (3d) 19 (1996) (Can.).

[FN282]. Stephen B. Garland, Methods of Medical Treatment Revisited, Patent World, August, 1997, at 7, 8.

[FN283]. Article 25 of the Patents Act 1977 (S. Afr.) states as follows:
(1) A patent may, subject to the provisions of this section, be granted for any new invention which involves an inventive step and which is capable of being used or applied in trade or industry or agriculture.
....
(9) In the case of an invention consisting of a substance or composition for use in a method of treatment of the human or animal body by surgery or therapy or of diagnosis practiced on the human or animal body, the fact that the substance or composition forms part of the state of the art immediately before the priority date of any claim to the invention shall not prevent a patent being granted for the invention if the use of the substance or composition in any such method does not form part of the state of the art at that date.
(11) An invention of a method of treatment of the human or animal body by surgery or therapy or of diagnosis practiced on the human or animal body shall be deemed not to be capable of being used or applied in trade or industry or agriculture.
(12) Subsection (11) shall not prevent a product consisting of a substance or composition being deemed to be capable of being used or applied in trade or industry or agriculture merely because it is invented for use in any such method.

[FN284]. Applications are examined only to the extent of basic formalities, but not content. It is the applicant's responsibility to ensure the proper scope of the invention is defined. If a patent's scope is too broad, it will invalidate the patent during litigation and damages may be sought against a party that knowingly tries to enforce an unenforceable patent.

[FN285]. Patent Cooperation Treaty (PCT), (Washington, 1970).

[FN286]. North American Free Trade Agreement, Dec. 17, 1992, art. 1709, at 3(a), 32 I.L.M. 605, 670-81.

[FN287]. Agreement On Trade-Related Aspects Of Intellectual Property Rights, Including Trade In Counterfeit Goods, Final Act Embodying The Results Of The Uruguay Round Of Multilateral Trade Negotiations, Apr. 15, 1994, art. 27, at 3(a), 33 I.L.M. 1, 83-111.

[FN288]. However, see Robert M. Portman, Legislative Restriction on Medical and Surgical Procedure Patents Removes Impediment to Medical Progress, 4 U. Balt. Intell. Prop. L.J. 91, 118 (1996) for an article expressing the opposite view.

[FN289]. Article 52(4) EPC.

[FN290]. Indeed, medical instruments seem to be patentable world-wide.

[FN291]. Patents Act 1990, Sections 133-135 (Austl.); see also, Patents Act 1953 § 51 (N.Z.), Patents Act § 39(4) (Can.).

[FN292]. Moufang, supra note 10, at 48; support for compulsory licenses may be found in Section 24, Patent Act (F.R.G.).

[FN293]. Plant Variety Protection Act, 7 U.S.C. § 2404 (1994) (U.S.).

[FN294]. Clean Air Act, 42 U.S.C. § 7608 (1994) (U.S.).

[FN295]. 28 U.S.C. § 1498 (1994) (U.S.).

[FN296]. Steven L. Nichols, Hippocrates, the Patent-holder: the Unenforceability of Medical Procedure Patents, 5 Geo. Mason L. Rev. 227, 260 (1997).

[FN297]. Id. citing, Ploof v. Putnam, 71 A. 188, at 189 (Vt. 1908)

[FN298]. Katopis, supra note 175, at 359.

[FN299]. For an extensive discussion regarding prior user rights, see Katopis, supra note 175, at 361.

[FN300]. Id. at 365.

[FN301]. Gocyk-Farber, supra note 39, at 1558.

[FN302]. Id.

[FN303]. Id. at 1559.

[FN304]. Anaesthetic Supplies, supra note 223, at 142.

[FN305]. See, e.g., Eli Lilly & Company's Application, [1975] RPC 438, 445 (Austl, Pat. Off.) ("the reasons for such an exclusion appear to us to be based in ethics rather than logic."); Anaesthetic Supplies, supra note 223, at 153 ("The decisions of the English courts base their conclusion that methods of treating the human body are to be excluded from patentability on a variety of grounds, primarily grounds of ethics rather than logic, and they are not the subject of any fully developed reasoned considerations."); Moufang, supra note 10, at 33; Thums, supra note 1, at 426.

END OF DOCUMENT

APPENDIX B

Claims Appendix

Claims 18, 20, 23-26, 31, and 34-36

U.S. Patent Application No. 08/817,704

Filed August 25, 1997

18. A method of treating morning stiffness, loss of grip strength, painful joints, or swollen joints in a rheumatoid arthritis patient suffering from morning stiffness, loss of grip strength, painful joints, or swollen joints, consisting of

identifying that a patient suffers from morning stiffness, loss of grip strength, painful joints, or swollen joints and

administering to the patient that suffers from morning stiffness, loss of grip strength, painful joints, or swollen joints a morning stiffness, loss of grip strength, painful joints, or swollen joints an effective amount of erythropoietin over a treatment period;

identifying that said patient that suffers from morning stiffness, loss of grip strength, painful joints, or swollen joints, has, after said treatment period in comparison to before said treatment period, a lower level of morning stiffness, loss of grip strength, painful joints, or swollen joints.

20. A method of ameliorating an erythrocyte sedimentation rate or C-reactive protein level in a rheumatoid arthritis patient in need of such amelioration, consisting of

identifying that a patient is in need of such amelioration;

administering to the patient an erythrocyte sedimentation rate or C-reactive protein level activity ameliorating effective amount of erythropoietin over a period; and

identifying that the erythrocyte sedimentation rate or C-reactive protein level in said patient has been ameliorated.

23. The method of claim 18, wherein the erythropoietin is human erythropoietin.

24. The method of claim 18, wherein the erythropoietin is of recombinant origin.

25. The method of claim 20, wherein the erythropoietin is human erythropoietin.

26. The method of claim 20, wherein the erythropoietin is of recombinant origin.

31. The method of claim 20, wherein the period comprises 6 weeks of treatment.

34. The method of claim 18 wherein the treatment period is at least 3 weeks.

35. The method of claim 20 wherein the treatment period is at least 3 weeks.

36. The method of claim 18, wherein the treatment period comprises 6 weeks of treatment.